The health impact of health and nutrition claims in the UK, Germany, the Netherlands, Spain and Slovenia.

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A thesis submitted for the degree of Doctor of Philosophy in Population Health

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Abstract

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Background: Health-related claims (HRCs) are statements to be found on food packets that convey the nutritional quality of a food and/or its impact on a health outcome. It is unknown whether HRCs improve, hinder, or have negligible effects, on diet and/or health.

Aims: To estimate the impact of HRCs on dietary choices; measure the prevalence of HRCs in five European countries, and the nutritional composition of foods carrying HRCs; compare nutrient profile models aimed at regulating HRCs; and model the impact of HRCs on non-communicable disease (NCD) mortality.

Methods: This thesis reports on a systematic review of the impact of HRCs on dietary choices; a survey of HRCs on pre-packaged foods available to purchase in the UK, Germany, the Netherlands, Spain, and Slovenia; analyses of the nutritional quality of foods that carry HRCs and foods that do not; and the development of a model to predict the current impact of HRCs on NCD mortality in the UK, and the impact of using a nutrient profile model to regulate the use of HRCs.

Results: Foods carrying a HRC are 75% (OR 1.75, 95% Confidence Intervals [95% CI] 1.60, 1.91) more likely to be chosen than identical foods without a HRC. In the five countries surveyed, 26% (95% CI 24%, 28%) of foods carry a HRC and these foods, on average, have a more favourable nutritional composition than foods without a HRC. Modelling suggests that removing HRCs from food labels would result in an additional 2808 deaths per year (95% Uncertainty Intervals -2993, 7392), and that regulating the use of HRCs with a nutrient profile model (such that only foods that pass the model can carry a HRC) would also be detrimental to health. However, the uncertainty intervals associated with these results are large and cross zero. The largest contributor to this uncertainty is the insufficient statistical power of the food composition data.

Discussion: Regulation of HRCs in the EU is the focus of much debate. Current EU law requires the development of a nutrient profile model for their regulation. In order to make an evidence-based health impact assessment of such regulation it would be necessary to collect data on a much larger dataset of foods than that used for this thesis.

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CHD: Coronary heart disease

CI: Confidence Interval

CVD: Cardio-vascular disease

C#: Cluster/class

EC: European Commission

EFSA: European Food Safety Authority

EU: European Union

EUFIC: European Food Information Council

FOP: Front of Pack

FSA: Food Standards Agency

FSANZ: Food Standards Australia New Zealand (formerly Australia New Zealand Food Authority (ANZFA)

GBD: Global Burden of Disease

GNPD: Global New Products Database (Mintel)

HC: Health claim

HRIC: Health-related ingredient claim

g: Grams

ICF: International Classification of Functioning, Disability and Health

Kcal: Kilocalorie

Kj: Kilojoule

LCF: Living Costs and Food (Survey)

MUFA: Monounsaturated fatty acids

MYE: Mid-year estimate

Ncom: Nutrient comparative claim

Ncon: Nutrient content

NOF: Nutrient and other function

NPSC: Nutrient Profiling Scoring Criterion

mg: Milligrams

ml: Millilitre

NC: Nutrient claim

NCD: Non-communicable disease

NDNS: National Diet and Nutrition Survey

OFCOM: Office of Communications (UK)

OR: Odds ratio

PABAK: Prevalence adjusted bias adjusted kappa

PUFA: Polyunsaturated fatty acids

RDI: Reference Daily Intake or Recommended Daily Intake

RDR: Reduction disease risk

RR: Relative risk

UI: Uncertainty Interval

UK: United Kingdom

US: United States of America

US FDA: US Food and Drug Administration

WHO: World Health Organization

/day: per day

Contents

1. Introduction

Health-related claims are short statements that convey a food's nutritional quality and/or an associated health-outcome. The overarching aim of this thesis is to ascertain whether health-related claims on food labels have an impact on diet and/or health. This thesis uses data from labels of pre-packaged foods available to purchase in the United Kingdom (UK), Germany, the Netherlands, Spain, and Slovenia.

In the first part of this chapter I provide an overview of the literature and policy background for the use of health-related claims on food labels. The second part of this chapter is a summary of the aims for each chapter. The methods for the thesis are discussed in greater detail in Chapter 3.

Part 1 Diet, health, and food labels

Non-communicable diseases

Non-communicable diseases (NCDs) are a major cause of ill-health and premature death. The World Health Organization (WHO) estimates that two thirds of premature deaths in Europe are due to four NCDs; cardiovascular disease (CVD), diabetes, cancer, and chronic respiratory disease [1]. Within the five countries examined in this thesis, the UK, Germany, the Netherlands, Spain and Slovenia, NCDs account for approximately 90% of all deaths [2].

A poor diet is a major modifiable risk factor for NCDs. The Global Burden of Disease (GBD) study estimates that, in 2015, more than 12 million deaths (globally) were due to dietary risk factors [3]. Within the European Union (EU), more than a million deaths were associated with dietary risks. Diets high in sodium, diets low in whole grains, and diets low in fruits were three leading dietary risks in the EU (Table 1.1).

Table 1.1 Diet-related deaths, in thousands, per 100,000, in 2016 [4]
(Deaths for both sexes and all ages, uncertainty intervals in parentheses, ranking in brackets)

Deaths due to diets…	**Global**	**Germany**	**The Netherlands**	**Spain**	**Slovenia**	**United Kingdom**
...low in whole grains	33.8 (22.5, 47.4) [1]	56.5 (36.6, 81.6) [1]	34.7 (24.4, 47.0) [1]	20.6 (10.7,33.5) [2]	51.5 (33.6, 73.5) [1]	35.9 (23.9, 50.2) [1]
...low in fruits	31.9 (19.6, 46.6) [2]	40.2 (21.4, 62.1) [3]	20.9 (10.3, 33.2) [2]	13.9 (5.6, 24.8) [7]	26.0 (12.4, 43.2) [5]	30.2 (17.3, 44.0) [2]
...high in sodium	31.3 (8.9, 60.9) [3]	35.4 (1.4, 89.2) [5]	16.8 (0.3, 42.6) [5]	19.0 (0.3, 51.0) [3]	50.0 (9.8, 104.8) [2]	7.0 (0.0, 27.5) [10]
...low in nuts and seeds	29.2 (18.2, 40.1) [4]	47.3 (28.0, 67.8) [2]	19.4 (11.5, 28.5) [3]	25.8 (15.6,37.0) [1]	39.3 (23.9, 56.4) [3]	28.5 (17.3, 40.1) [3]
...low in seafood omega-3 fatty acids	20.8 (8.7, 34.1) [5]	32.0 (12.6, 53.4) [6]	14.2 (5.7, 24.3) [6]	15.5 (6.1, 26.6) [5]	22.7 (9.0, 40.6) [6]	17.0 (6.8, 29.0) [5]
All dietary risks	**139.4 (119.0, 161.1)**	**233.0 (193.8, 275.7)**	**121.8 (100.3, 146.6)**	**119.5 (96.6, 145.1)**	**204.1 (163.3, 251.1)**	**139.9 (123.0, 158.0)**

Diet

The WHO recommends that the adult diet should contain ≤ 10% (preferably ≤ 5%) of energy from free sugars, ≤ 30% of energy from total fat, and ≤ 5g per day (g/day) of salt. The WHO also recommends that adults reduce their saturated fat consumption and eliminate trans-fat from their diet. The WHO encourages consumption of fruit and vegetables (at least 5 portions or 400g/day), legumes, nuts and wholegrains [5].

Within the UK, the dietary guidelines are that as a percentage of food energy, free sugars should contribute ≤ 5%, total fats ≤ 35%, and saturated fats ≤ 11% [6]. Salt intake should be limited to 6g/day (2363mg of sodium) [7], and adults should consume at least 30 g/day of fibre

[6]. The food-based recommendations are that adults should consume at least 5 portions of fruit and vegetables per day (approximately 400g/day) [8], should consume two portions of fish (one of which should be oily fish) a week [9], and limit red and processed meat intake to no more than 70g/day [8].

Estimates for the average population nutrient intakes in the UK have generally found that diets are suboptimal: The National Diet and Nutrition Survey (NDNS) shows that total fat, saturated fat, free sugars, and salt intakes are higher than the recommended amounts, whereas fruit and vegetable, fibre, and oily fish intakes are lower than the recommendations [10]. The NDNS is a survey of food consumption in the UK, which involves a representative sample of participants measuring their food consumption over a period of three-four days. Survey weights are applied to the results in order to adjust for non-response bias. Direct comparisons of population level consumption data in other countries are difficult due to different methods for sampling and data collection, definitions, and times of data collection.

Improving diet

Modelling studies have estimated that, in the UK alone, up to 33000 deaths per year could be averted if dietary recommendations were met [11]. This represents 14% of deaths from coronary heart disease, stroke, and cancer in the UK. Registered death data for all-cause mortality the UK in 2012 was 514,078 deaths. Therefore, improving diet should be considered a public health priority as, because poor diets are so prevalent and poor diets are strongly associated with poor health, even small dietary changes can have large population effects when scaled up [11].

Promoting healthier food choices is an important step to improving diet. The WHO and the UK government [12-14] agree that promoting heathier food choices is an important component of

improving diet. Food labelling has been identified by some as one potential tool to promoting healthier choices (e.g. [15]).

Methods of improving diet

Interventions to improve diet may take an individual-level or a population-level approach. Individual-level approaches are delivered to an individual or a small group of individuals at a time. Individuals receive the intervention because they have been identified as either being in a high-risk population and/or already require treatment for the condition that the intervention targets. An individual-level approach to improve diet may involve a healthcare or nutrition professional giving dietary advice or feedback to an individual who may already present with a diet-related condition or be at high-risk of developing a condition.

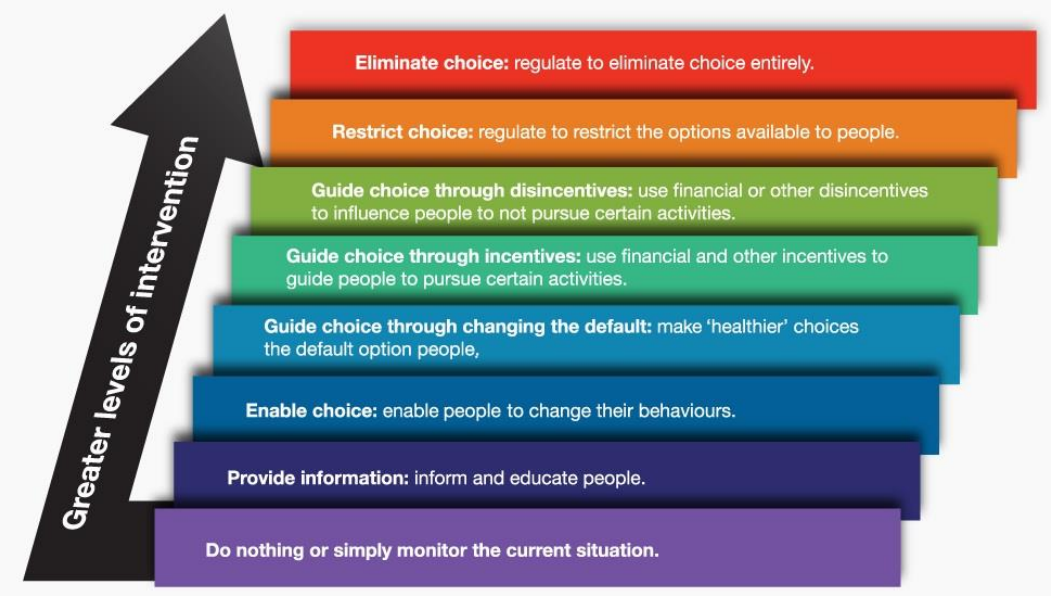
Individual-level approaches can be expensive and time-consuming to administer and only a small proportion of the population may benefit from the intervention. Such approaches may not be the most appropriate when the problem and/or the associated risk factors are highly prevalent throughout the population.

An alternative approach is to deliver interventions at a population-level. Population-level approaches are delivered to large groups or entire populations often regardless of the individuals' likelihood of having (or developing) the targeted condition. Population level interventions include mass-media campaigns such as the UK Government's Change4Life campaign [16]. This campaign was delivered via various platforms including TV advertising, mobile-phone apps, and social media. The aim of the campaign was to educate people of the risks associated with sedentary behaviour and poor diets and to encourage healthier diets and increased physical activity. However, the success or efficiency of such approaches is heavily reliant upon individuals being engaged with the intervention.

Population-level interventions vary in how much 'agency' is required by the individual in order for the intervention to be effective. With regard to improving diet, removing unhealthy foods from the marketplace involves little involvement from the individual in order to be effective. Such interventions tend to have a greater impact than interventions that require the individual to be engaged with and motivated by the intervention. Interventions that require high levels of agency may reinforce and/or promote health inequalities as, for example, individuals with a greater understanding of health and/or nutrition information (or health literacy) may be likely to engage with the intervention (or health behaviours) and health literacy tends to be greater in some demographic groups compared to others (e.g. [17, 18]). However, interventions requiring lower levels of agency, such as removing products from the marketplace, may be perceived as too intrusive or too paternalistic to be applied [19].

The Nuffield Intervention Ladder (Figure 1.1) is a depiction of how policy options may impact upon individuals' choices. Policies that are considered more restrictive or intrusive are at the top of the ladder and interventions that allow for more individual autonomy are at the bottom. Interventions at the top of the ladder are thought to require more justification and may be harder to gain public acceptance as they impact upon individual's choices. In contrast interventions at the bottom of ladder require less justification and may be more easily accepted by the public. A study of health policies found that governments tend to prefer policies that rely on individual agency rather than changes to the environment – despite the evidence suggesting that the latter may have a greater impact upon health [19].

Figure 1.1 The Nuffield Intervention Ladder [20, 21]



Food labelling is used to provide information to the consumer but it is also space for promotion. Food labels could be used as a population-level approach to improve diet by promoting healthier products. Such an approach should be more easily accepted by the public and has fewer ethical issues than approaches higher up the Nuffield Intervention ladder, such as restricting or removing foods with a less favourable nutritional composition from the marketplace.

Food labelling

Food labelling can be defined as "any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food..." (page 25, [22]).

There is a wide variety of information presented on food labels some of which may be more relevant to health than others. This type of information can be defined as "health-related food

labelling" and refers to; lists of ingredients, nutrient declarations, supplementary nutrition information, and nutrition and health claims [23].

The type and amount of information provided on food labels may vary across countries. The International Network for Food and Obesity/NCD Research, Monitoring and Action Support (INFORMAS) aims to monitor the provision of health-related food labelling but to do so consistent definitions are required to make results comparable across countries [24]. The INFORMAS developed a taxonomy (Figure 1.2) for such studies [23].

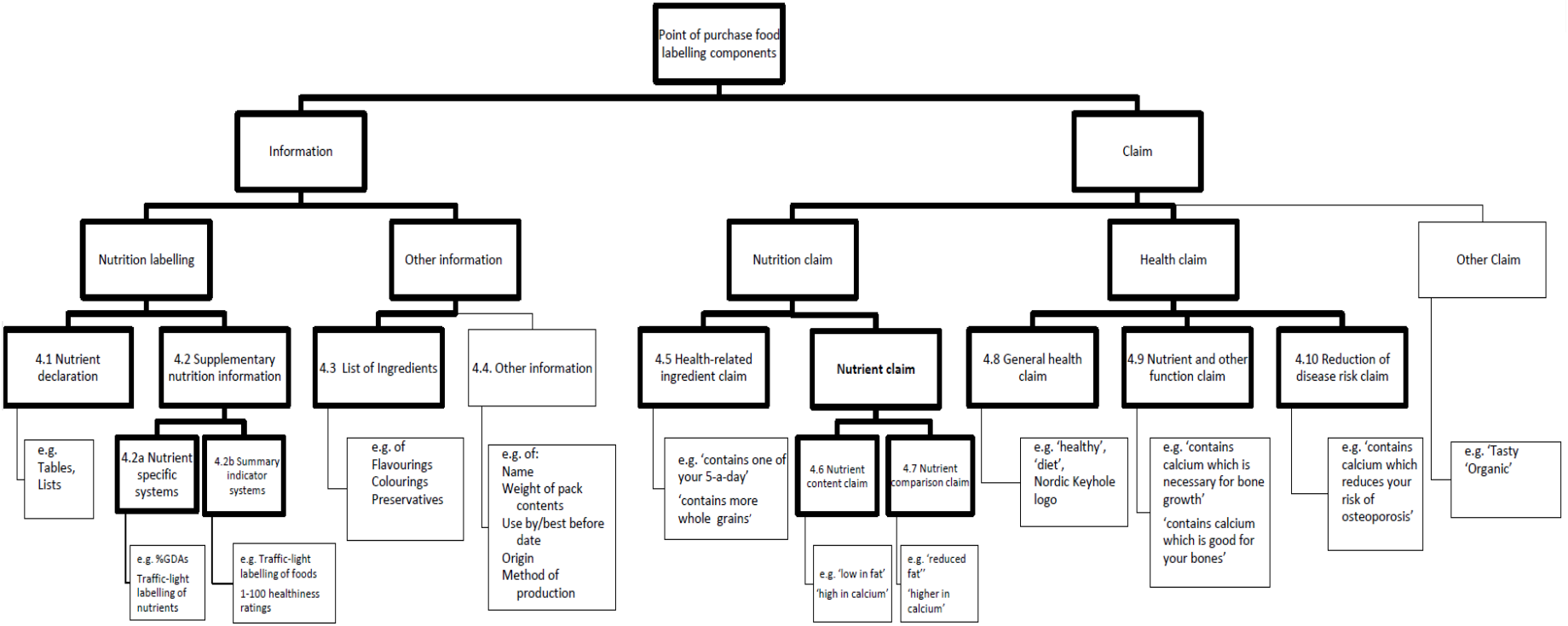
The INFORMAS taxonomy separates the information presented on food labels into 'information' and 'claim'. Within this thesis I focus on health and nutrition claims (or 'health-related claims'). A brief background of the 'Information' section of the taxonomy is given for context.

Food labelling regulations in the EU

Within the EU, the rules for food labelling are set out in Regulation (EC) 1169/2011 [22]. This regulation came into effect in December 2014 and combines and replaces two former directives; Labelling, presentation and advertising of food stuffs 2000/13/EC [25] and Nutrition labelling for foodstuffs - 90/496/EC [26].

Nutrition labelling can be defined as "a description intended to inform the consumer of nutritional properties of a food." And nutrient declarations can be defined as "…nutrition labelling which is 'a standardized statement or listing of the nutrient content of a food" [27].

Figure 1.2 INFORMAS Food labelling taxonomy [23]



Regulation 1169/2001 outlines which information is mandatory on a food label and the rules for information provided on a voluntary basis. For example, manufacturers must provide the product name, list of ingredients, and the manufacturer's address. From December 2016 manufacturers must also provide nutrition labelling – more specifically, nutrient declarations for; the energy, and levels of; fat, saturated fat, carbohydrates, sugars, protein, and salt (Article 29). In addition to this, manufacturers may choose to provide the levels of monounsaturated fat (MUFA), polyunsaturated fat (PUFA), polyols, starch, fibre, and vitamins and mineral content. Although the latter information is not mandatory there are still rules for where it is provided.

Nutrition labelling

Nutrition labelling is commonly found on food labels in the EU, even prior to the current legislation. A European survey of nutrition labelling found that 85% of products provided nutrition labelling and that this information was often presented as a table or list of nutrient content on the back of the label [28].

The European Commission (EC) has identified nutrition labelling as an important tool for consumers to make informed choices (page 19,[22]). Consumers view the nutrition label as a credible source of information and value the information provided [29]. People who read the nutrition label tend to have more nutritionally favourable diets than people who do not read the nutrition label [30, 31]. However, their improved quality of the diet may be due to other factors, for example – a pre-existing interest in health [32] and not label use alone.

The efficacy of nutrition labels to improve diet may be limited if it is only appealing to those who already have an interest in nutrition and/or health, or if the label can only be understood by those with advanced nutritional knowledge (sometimes referred to as the "nutrition elite") [33]. Some groups, such as older obese adults, may find nutritional labelling difficult to

understand [30]. Several systematic reviews have concluded that consumers would benefit from interpretative aids to help them understand the information more quickly [31, 34].

Interpretative aids could take a variety of formats. Referring to INFORMAS taxonomy, some interpretative aids could be categorised as Supplementary Information. This information could be nutrient specific (e.g. traffic light labelling) or they could provide an overall score or rating of a food's nutritional quality (e.g. health rating systems).

Consumers vary in their preferences of more simplified formats of nutrition labelling [29]. Some consumers prefer formats where some factual information is provided and some interpretation of that information is offered. For example, with traffic light labelling the levels of energy, total sugars, total fat, and sodium in a food are displayed on the front of pack. The colours red, amber and green are used on each nutrient to indicate whether a food has high, medium, or low levels of each nutrient. The consumer can evaluate the information provided. With more directive formats less information is provided but more salient advice is given (for example a health-related claim). This type of format is thought to require less cognitive involvement from the consumer [35, 36] which may be of benefit to improving food choices where a large amount of choices are often habitual [37].

Health-related claims

Health-related claims are verbal statements or visual images that refer to the nutritional and/or health-promoting qualities of a food. In this thesis 'health-related claims' refers to both health and nutrition claims. A 'nutrition claim' refers to any claim which "*states, suggests or implies that a food has particular beneficial nutritional properties due to…the energy (calorific value)...or the nutrients or other substances…*" (page 9, [38]). *A 'health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a*

food or one of its constituents and health" (page 9, [38]). The sub-types of health and nutrition claims are discussed in Chapters 3 and 4.

Regulation of health-related claims in the EU

Within the EU, the use of health-related claims on food labels, or in promotional materials and activities, is regulated by Regulation (EC) 1924/2006 [38]. This regulation came into effect in July 2007, however manufacturers were given additional time to comply with some aspects of the regulation, for example, manufacturers were allowed to continue selling foods that had already been labelled until August 2009 (Article 28).

In Regulation (EC) 1924/2006 it states that:

"…nutrition and health claims must not:

(a) be false, ambiguous, or misleading;

(b) give rise to doubt about the safety and/or nutritional adequacy of other foods;

(c) encourage or condone excess consumption of a food;"

(page 10, [38])

The general conditions for the use of nutrition and health claims are outlined in Article 5 of Regulation (EC) 1924/2006. The main points are

- The amount of the nutrient, ingredient, component that is present, absent, or reduced, must represent amounts that have been shown (through scientific evidence) to have a beneficial effect on health
- The amounts of nutrient, ingredient, component that for which the effect is claimed must be at levels that can be achieved through 'reasonable' consumption of the food.

- The use of nutrition and health claims is only permitted if it is understood by the average consumer.

Prior to Regulation (EC) 1924/2006, EU member states had different rules for the use of health-related claims on food labels, this may have hindered the movement of goods and services between countries if two countries had conflicting food labelling laws. The FLABEL (Food Labelling to Advance Better Education for Life) project confirmed these differences through conducting surveys of nutrition labelling in the 27 EU Member States and Turkey between September 2008 - April 2009 –prior to the August 2009 deadline [28].

From December 2016 manufacturers must provide nutrition labelling on foods (Regulation (EC) 1169/2011, [22]), although exemptions are granted for foods with small packaging sizes and/or foods, certain unprocessed foods, and/or foods where "…nutrition information may not be a determining factor for consumers' purchasing decisions…" (page 22, [22]). Prior to this the provision of nutrition labelling was only mandatory when a health or nutrient claim was present on the food label or in the marketing of a product. This was to provide the consumer with an opportunity to evaluate the nutritional composition of a product and/or assess the truthfulness of the claim (Article 49,[22]). However, if nutrition information is not easily understood by the average consumers then it follows that consumers may still be misled.

Consumers may find some types of claims easier to evaluate than others. For example, a consumer wishing to assess the truthfulness of a 'low in fat' claim may read the nutritional composition list and check the amount or proportion of fat a food contains. The truthfulness or accuracy of a health claim is not so easily evaluated -it requires some knowledge of nutrients, their role(s) in normal functioning, and the association between diet and health. Therefore, some consumer protection is required to prevent the potential exploitation of

consumers and to give consumers some confidence in the validity of any claims, particularly health claims, being made.

Substantiation of claimed effect on health

All health-related claims used on food labels or promotional activities in the EU must be approved by the EC. The nutrition claims that have been authorised for use are listed in the Annex to Regulation (EC) 1924/2006. There are 29 nutrition claims listed, 22 of which have nutrient-specific rules for their use for example, in order to use a 'low sugars' claim the food may not contain more than 5g per 100g of total sugars if it is a solid food or 2.5g total sugars per100ml if the food is a liquid.

The process for using a health claim differs. The EU Register of nutrition and health claims made on foods contains the health and nutrition claims that have been submitted for approval [39]. In order to use a health claim, manufacturers must first check the Register to see whether a similar health claim has already been submitted for approval. If the claim has been approved, then the conditions of its use will be given in the Register. If a claim has been refused then the reason(s) are given. A separate list exists for submitted claims that have not yet received a decision, submitted function claims that have been rejected as the EC does not consider as 'function claims', and claims that the EC does not consider as relating to human health.

If the claim has not been submitted before then it must go through the substantiation process which involves manufacturers submitting a dossier containing scientific evidence that supports the claim. There is detailed guidance on how claims should be substantiated in Regulation 353/2008 [40]. For example, the supporting evidence must consist of studies with humans.

Manufacturers first submit their application to the appropriate EU Member State/National Authority. The Member State is responsible for checking that the application is complete and

ensuring that the claim being made is not either a medicinal or non-specific claim (as per the rules outlined in Directive 2000/13/EC [25]). The Member State may at this point refer to additional rules on the grounds of public health consumer protection (Article 39, [22]).

If the Member State is satisfied with the application they then forward it the European Food Safety Authority (EFSA) for approval. EFSA evaluates the applications (usually with 5-6 months) and publishes its opinion in the EFSA journal [41]. EFSA then sends its opinion to the EC where the claim is reviewed by a committee comprised of representatives of all member states and EFSA. Once an agreement is reached, a regulation on the claim is drafted, and the Committee and European Parliament vote to accept or reject the proposed regulation.

This process was established to ensure that health claims are *'truthful, clear, reliable and useful to the consumer in choosing a healthy diet'* (page 7, [38]). However, health claims can be technically true (i.e. substantiated with evidence) and still have the potential to be misinterpreted by consumers.

The substantiation process generally favours specific terms and effects as these can be supported by evidence. However, some consumers may find it difficult to understand detailed scientific terms and prefer simplified, short terms [42]. However, using broader terms such as 'healthier' or 'goodness' may make the claim more easily understood but may also make it less accurate and have a greater potential to be misleading [43].

Nutrient compositional criteria – is a nutrient profile model needed?

Nutrient profiling is *"the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health"* [44]. The algorithms behind these classifications or rankings are called nutrient profile models. Nutrient profiling has numerous applications, for example, helping consumers identify 'healthier' foods

through support of health logo schemes, and also identifying 'less healthy' foods e.g. through the regulation of TV advertising of foods to children [45].

In Regulation 1926/2006 it states that nutrient profile models should be used to prevent the overall nutritional quality of foods being masked by the presence of a health claim. This would be an addition to the current conditions to use of health claims so that only foods that pass a nutrient profile would be eligible to carry a health claim. However, this part of the legislation has not been enacted and the EC is currently evaluating whether Regulation 1926/2006 is 'fit for purpose'. Part of this evaluation shall involve whether the regulation would be improved by the use of a nutrient profile model and estimating the cost of not having done so [46].

Several countries already use a nutrient profile model to underpin their health-related claim regulations. The Food Standards Australia New Zealand (FSANZ) have been using the Nutrient Profiling Scoring Criterion (FSANZ NPSC) to regulate health-related claims since 2016 [47].

Currently, there is insufficient evidence to assess whether a nutrient profile is needed as little is known about how health-related claims impact on diet and/or health. This is due to a lack of knowledge on how health-related claims influence consumer behaviour, how prevalent health-related claims are, and the general nutritional quality of foods that carry health-related claims compared with those that do not. In this thesis I aim to address these areas.

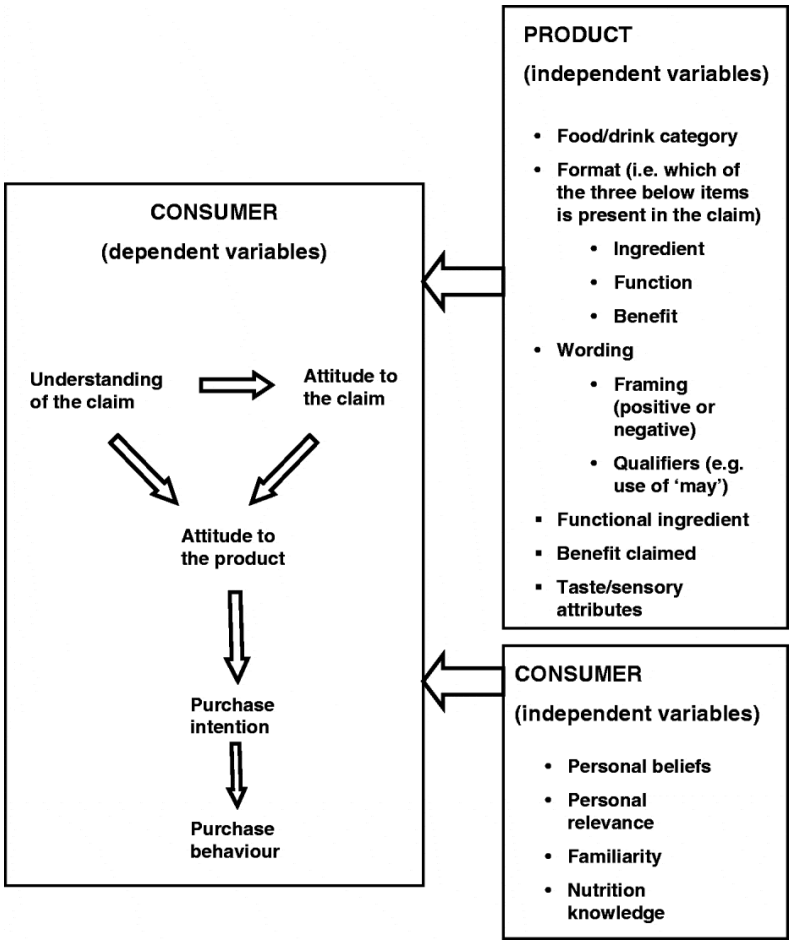
Effects of health-related claims

Previous studies on the effects of health-related claims often have contradictory results. However, one consistent finding is that consumers often state that health is an important factor in their food choices and that they have an interest in health-related claims [34].

Health-related claims may change behaviour through a number of pathways. The conceptual framework in Figure 1.3 was developed by Wills et al (2013, [34]) and follows a review of

research on health-related claims. Within this framework purchase behaviour is determined by intent, which in turn, is determined by the consumer's attitude towards the product carrying the claim (or 'carrier-product'). The consumer's attitude to the product is formed by their understanding of and attitude towards the claim. The process is also influenced by characteristics of the product carrying the claim and the consumer's characteristics.

Figure 1.3 Conceptual model for the use of health-related claims [34]



Effects on consumers attitudes

In Regulation (EC) 1924/2006 it states that "The use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim" (page 12, [38]). However, how consumers understand and perceive health-related claims is influenced by the consumer's characteristics such as their gender, socio-economic status, level of education attained, and their interest in health and nutrition. Reviews of consumer understanding of health-related claims have found that middle-aged women of higher socio-economic status and higher-levels of education tend to have a greater interest in and understanding of health and health claims [29, 48]. Due to the importance of the consumer's characteristics some researchers argue that the term 'average consumer' is a misnomer and should instead be replaced with 'target consumers' [48].

Another review suggested that the relevance that a health-related claim has to a consumer may be of greater importance than their socio-demographic characteristics [49]. In studies where female preferences for health-related claims were found the claims being tested were often more relevant to issues traditionally viewed as female health issues (for example, claims relating to bone health as opposed to claims relating to the heart). These gender effects were reduced in studies where the claims being tested were not considered so gender-specific [49].

The personal relevance of a claim may be important due to the level of risk consumers perceive they have of developing a condition. For example if the claim relates to a condition that they have, then consumers may place extra importance on the benefit (or reduction of risk) promoted by the claim and may be more willing to buy the product [50].

Effects on consumer behaviour

Health-related claims may help to improve the diet if health-related claims help consumers identify and consume foods with a more favourable nutritional profile. Reviews of studies on

health-related claims have found that products carrying health-related claims are often perceived as being healthier than similar foods that do not carry claims, and consumers say they are more likely to buy them [34, 49, 51, 52] (however, the size of this effect has not previously been estimated in a meta-analysis). As such, they may impact upon dietary choices however, these effects can be small and mediated by consumer and product characteristics [49] and may not consistently influence dietary choices [53].

Increased intent to buy products often doesn't translate into increased purchases. For example, in a think-aloud shopping task consumers frequently said that they were interested in health and used health-related claims (in this instance, health logos) when buying products but this was not reflected in their actual product choices [54].

Consumers do not base their choices solely on health - other factors such as price, taste, and brand preference also play a role in dietary choices. Some studies have suggested that the presence of health-related claims may make a product less appealing to consumers as they may believe that unhealthy foods taste better than healthier foods [55]. However, others have found that the perceived healthiness of a food led to an increase in consumption; in one study participants consumed up 35% more when cookies were labelled as 'healthy' then when they were labelled as 'unhealthy' [56].

Health-related claims may have detrimental effect on health if they encourage excessive consumption of a product. The presence of health-related claims may lead to a lowered sense of guilt associated with consumption. Wansink and Chandon (2006, [57]) measured consumption of confectionery and found that consumers consumed significantly more when the confectionery was labelled as 'low fat' and this effect was greater for overweight consumers than for normal weight consumers. They then conducted a similar experiment this time asking consumers to estimate the number of calories they consumed and estimates for portion sizes, and they also used an additional test product (granola). They found that labelling

either the confectionery or the granola as 'low fat' increased consumption. They also found that consumers consistently underestimated the amount of calories they had consumed and overestimated the correct serving size when the 'low fat' label was applied. Furthermore, participants reported lower levels of guilt associated with food consumption when the 'low fat' label was applied. Wansink and Chandon referred to these effects as 'health halos' and suggested that they could be easily mitigated by challenging consumers perceptions of healthiness [58].

Health-related claims may lead to consumers attributing additional benefits to a product which are not referenced in the claim ('halo effect') and/or attributing inappropriate health benefits to a product ('magic-bullet effect'). Roe et al (1999) also found that when products carried a health-related claim they neglected more detailed information on the back of pack (such as nutrition labelling). This effect was greater for health claims then for nutrition claims [51].

The effect of health-related claims on consumer behaviour remains unclear. Some suggest there are small effects [49], whereas other studies suggest substantial increases in consumption [56, 57]. The conflicting results may be due to, as the Framework in Figure 1.3 suggested, differences in the type of product, the type of claim, and the type of participants involved. In the next chapter I conduct a systematic review of studies that examine the effect of health-related claims on dietary choices.

Effects on Manufacturers

The conceptual model in Figure 1.3 shows how consumers may respond to health-related claims. How manufacturers use health-related claims is also very important. If consumers respond positively to health-related claims then manufacturers may wish to capitalise on this by increasing the number of products that carry health-related claims. This could lead to

product reformulation so that they are eligible to carry such claims and in particular health symbols.

In an Australian study of Kellogg's ready-to-eat breakfast cereals 12 products were chosen for reformulation with the 'Pick the Tick' health logo criteria for sodium being used as a target. After the reformulation process, on average, there was a 40% reduction of sodium, translating to 235 tonnes of salt per year, or 13g of salt per person, in 1997. However 7 of these products were still unable to carry the logo even after the reformulation, the 5 products that became eligible were responsible for 53% of the reduction [59].

Similarly, a study of the effect of the 'Pick the Tick' logo on reformulation (of existing products) and formulation (of new products) in New Zealand found that there was a 61% reduction in the sodium levels in breakfast cereals, a 26% reduction for bread, and 11% reduction for spreads, between July 1998 and June 1999. Formulation of new products specifically to meet the criteria led to the removal of 21 tonnes of salt in a year [60]. These actions by food manufacturers could have a large impact on population health.

A much larger, and more recent, study examined the impact of a health logo in the Netherlands. In order for a product to be eligible to carry the logo (The Choices Logo) it had to pass a nutrient profile model. The manufacturers who joined the logo scheme, 47 in total, indicated whether the products that carried the logo were new products, or reformulated, or already complied with the nutrient profile model. In total, 821 products were examined. The study found that 51% of products were existing products that were already compliant with the nutrient profile model and 49% of products had been designed to comply with the nutrient profile model. Of the 821 products, 20% had been reformulated so that the foods passed the nutrient profile model, and 29% were newly developed products designed to comply with the nutrient profile model [61].

These studies were conducted in Australia, New Zealand, and the Netherlands between 1997 and 2009. The studies measured the impact of product reformulation due to one type of claim (health logos) on nutrient levels in foods available to purchase. In Chapter 7 of this thesis I model the potential impact of different health-related claims scenarios, including reformulation, on the average levels of nutrients in products, what impact this may have on diet, and subsequently, what impact it may have to diet-related mortality.

Summary

Very little is known about the impact of health-related claims on health due to serious holes in the literature that this thesis sets out to fill. These holes include: how prevalent health claims are; the nutritional quality of foods that carry health claims compared to those that do not; what influence health claims have on consumer behaviour. Without this information it is impossible to predict the likely impact of regulating health claims with a nutrient profile model, which is a currently proposed option for the EU.

Part 2: Thesis Summary

This part of this chapter outlines the aims of each of the rest of the chapters in this thesis and describes how they answer these research questions:

1. What is the effect of health-related claims on dietary choices?

2. What is the prevalence of health-related claims?

3. Do foods that carry health-related claims have a more favourable nutritional composition than foods that do not carry a health claim?

4. How do nutrient profile models used for the regulation of health-related claims differ in their evaluations of the nutritional quality of foods?

5a. What is the current effect of health-related claims on population-level non-communicable disease (NCD) mortality in the UK?

5b. What would be the effect on population-level mortality if health claims were only permitted on products that pass a nutrient profile model?

Chapter 2 - The effect of health-related claims on dietary choices

I conduct a systematic review of experimental laboratory-based studies and natural experiments examining the impact of health-related claims on pre-packaged food and drinks on purchasing behaviour. The primary outcome measure of the review is the increase in likelihood of purchasing products that carry health-related claims.

Chapter 3 - Methods

This chapter includes the methods for sampling and collecting data for a survey of health-related claims on pre-packaged foods. It also provides a brief description of the methods I use to answer each of the research questions listed above. Further details such as validity exercises, justification, and background literature will be included in the corresponding chapter.

Chapter 4 – The prevalence of health-related claims

The prevalence of health-related claims, on a multi-country basis, has not been previously measured using a random sample of food products, across all food categories. In this chapter I

estimate the prevalence of health-related claims using the database (described in the previous chapter).

Chapter 5 – The nutritional quality of foods with and without health-related claims

The database of foods described in Chapter 3 also contains nutritional composition data for each food sampled. The levels of the following nutrients (per 100g) were recorded from the food labels: energy, protein, carbohydrates, total sugars, total fat, saturated fat, fibre, and sodium. The nutritional quality of foods carrying health-related claims is assessed through comparing the mean level of these nutrients of products with health-related claims with the mean levels of nutrients of products without such claims.

Chapter 6 - Nutrient profile models used for the regulation of health-related claims

In the EU, it has been proposed that nutrient profiling should be used to regulate the use of health claims. In this way, foods would need to meet two criteria to carry a health claim: a) that EFSA agrees that there is sufficient evidence to support the health claim; b) that the food is defined as 'healthy' by a nutrient profile model. In this chapter I apply three models currently used, or proposed for use, for the regulation of health-related claims and assess their strictness and agreement.

Chapter 7 - Modelling the effect of health-related claims

Using the findings from previous chapters, I build a front-end model for the Preventable Risk Integrated Model (PRIME, [62]) to assess the effects of different health-related claim scenarios on the diet and the associated health outcomes with these changes.

Chapter 8 - Discussion

In this chapter I summarise the main findings from each chapter and discuss their policy and research implications.

2. Systematic Review of the effect of health-related claims on dietary choices

Introduction

In the previous chapter I discussed what health-related claims are, the rules on their use, and how health-related claims may be used by consumers. In this chapter I conduct a systematic review and meta-analyses of the effect of health-related claims on purchasing and consumption. The findings from this chapter, particularly from the meta-analyses, shall also be used and discussed in Chapter 7 where I model the effect of health-related claims on health outcomes.

This systematic review has been published/presented in the following places:

- an article in the International Journal of Behavioral Nutrition and Physical Activity [63]
- a poster presentation at The UK Society for Behavioural Medicine annual meeting [64].
- the protocol for the review was published on PROSPERO [65]

Background

Within the EU, the rules that govern health-related claims are set-out in the Regulation (EC) 1924/2006 [38]. The objective of this legislation is to ensure that health-related claims are "… clear, accurate and based on scientific evidence." [66]. The Regulation also states that health-related claims must not be "false, ambiguous or misleading" and should be easily understood by the average consumer. This may explain why much of the previous research has focussed

upon how health-related claims are understood by consumers (e.g. a review of this was presented by Williams in 2005 [52]) rather than the effects of health-related claims on purchasing and consumption behaviour.

There is little discussion in the Regulation that relates to the effect of health-related claims on purchasing or consumption. Although the Regulation does posit that health-related claims may be perceived as having a health advantage over foods without health-related claims which "…may encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice." (page 4, [38]). However it is not clear if this is true, and/or just how large this effect may be. The aim of this chapter is to estimate the size of this effect through a review of experimental studies.

The findings of this review will help to establish a context for the findings presented in later chapters. In Chapters 4 and 5 I estimate the prevalence of health-related claims on pre-packaged food labels, and then compare the nutritional quality of foods with health-related claims to foods that do not carry health-related claims. I then use these findings to model whether health-related claims have an impact on health outcomes (specifically the burden of NCDs in the UK). In order to build this model it is necessary to have a numerical estimate of the effect of health-related claims on purchasing and/or consumption.

There is considerable contention on the effect of health-related claims on dietary choices. There is some evidence that health-related claims may increase consumption for example Wansink and Chandon (2006, [57]) found that participants ate more of a snack food when it was described as 'low fat'. However, other studies have found that health-related claims reduce consumptions as they lower consumers' taste expectations [55, 67].

A variety of methods have been used to study the effect of health-related claims. Early research into the effects of health-related claims on dietary choices looked at the sales of

products before and after a claim was introduced. For example, one study examined population sales data of breakfast oats before and after a health claim was used and found that sales increased once a health-related claim was added to the packaging [68]. Whilst these types of natural experiments have substantial external validity the lack of control means that there may be other factors driving the sales increases for example promotional campaigns or price reductions.

In contrast to this, experimental studies in controlled environments allow for more precise manipulation of these factors and are easier to replicate compared to natural experiments. For example, discrete choice experiments in laboratory settings allow researchers to manipulate multiple attributes of a product and to then measure how these changes affect the participants' choices. Product attributes are systematically manipulated and presented to the participants in choice sets. In conjoint analyses it is assumed that the participants make trade-offs for the attributes they value and through this the utility of each attribute can be estimated. These types of studies of the effect of health-related claims on dietary choices have not been reviewed systematically.

Previous reviews of health-related nutrition labelling

Previous systematic reviews on dietary choices have examined the role of nutrition labelling in dietary choices [30, 31]. These reviews found that nutrition labels can be used to guide choices although this varies by population subgroup. However, there have been very few systematic reviews that specifically examine the effect of health-related claims. Schemilt, Hendry, & Marteau (2017, [69]) conducted a systematic review of the impact of nutrition claims on selection, consumption, and perceptions of food products but did not consider health claims in the review. Williams (2005, [52]) conducted a systematic review on consumer

understanding and use of health claims and found some evidence that claims may improve the quality of dietary choices. However, effects were not quantified.

Therefore, I conducted a systematic review of experimental studies to quantify the effect of health-related claims, on food labels presented in a retail setting (or a retail scenario in laboratory-based studies) on adults' dietary choices. The primary outcome of interest to the review was the likelihood of choosing a product when a health-related claim was present compared to when such a claim was not present. The secondary outcome of interest was the percentage change (from when a health-related claim was present compared to when such a claim was not present) in measured, actual or intended, consumption and/or purchases.

Research questions

The research questions for this chapter are:

Do health-related claims on food labels increase purchasing and/or consumption behaviour and intentions?

How much do health-related claims on food labels increase purchasing behaviour and intentions?

How does this effect differ according to the type of health-related claim? - E.g. do health claims have a greater impact than nutrition claims?

Methods

The protocol for this review was registered with PROSPERO in August 2016 (Systematic review registration number: CRD42016044042, [65]). The review was reported according to the PRISMA guidelines (the PRSMA checklist was published as Supplementary Information [63]).

The search strategy was created with input from an information specialist and designed to capture any study of the effects of food labelling. Terms related to participants or study designs were not included in the search strategy as I expected much heterogeneity. The searches were piloted in November 2015 and the finalised searches conducted in December 2015 and re-run in September 2016 to check for new studies. The search terms are presented in Appendix A. I searched MEDLINE, PsychINFO, Embase, CAB abstracts, Business Source Complete, and Web of Science/Science Citation Index & Social Science Citation Index. To be eligible for inclusion articles had to be written in English and published in a peer review journal. No date restrictions were placed on the search.

Selection of studies

An article was included if it was a controlled experiment that examined the effect of health-related claims on food labels on adults' actual food purchasing and/or consumption behaviour or intended behaviour. Pre- and post-studies that collected longitudinal individual level data or population level data on real shopping behaviour were eligible. The health-related claim had to be presented in a retail setting or scenario (e.g. supermarkets) and not a food service setting or scenario (e.g. menus, canteens etc.). The decision to focus on food labels was made as the analyses performed later in this thesis relate to a sample of pre-packaged foods as opposed to health-related claims presented in other formats such as advertising materials.

For the purposes of this review an appropriate control was defined as the same product without a health-related claim but similar in all other aspects. Non-health related claims (e.g. taste or organic claims) were not considered to be appropriate control claims due to evidence of a taste/health association with food choices [55, 67].

The definitions and categorisations of health-related claims are those proposed by the International Network for Food and Obesity/non-communicable disease Research, Monitoring

and Action Support (INFORMAS) [23] which are based on the definitions of the Codex Alimentarius Commission (Codex) [70]. Definitions and examples of sub-types of health-related claims are discussed in greater detail in the next chapter (Chapter 3 – Methods). Only explicit health-related claims were considered in this review. Implicit claims, for example a picture of a person running or a heart shaped logo (without underlying nutritional criteria for its use), were not included. Health-related claims could be presented as text, a symbol or a combination of both.

Studies that solely examined children's and/or adolescents' dietary choices were not included, neither were studies that were concerned with the purchases of; infant and baby foods including follow-on milks, foods for specific nutritional uses, alcoholic beverages, and vitamins and mineral supplements. This is because the rules governing their use differ to conventional pre-packaged foods. Studies that estimated the maximum monetary amount participants were willing to pay for a product with specific attributes were excluded. Studies that presented the health-related claim as part of a wider intervention (e.g. healthy eating initiatives, weight loss groups etc.) were also not included.

Data extraction, synthesis, and analysis

The database search results were imported into Endnote V7. I completed the first screen of titles to remove any duplicate references and studies that were clearly unrelated to the systematic review. Full text articles were obtained when the title and abstract suggested that the study met the inclusion criteria. The full text was also sought when there was ambiguity about a paper's relevance to the review. Another researcher (Dr Peter Scarborough) assessed 10% of the references (minus records excluded at the title screen stage) in order to check for any disagreements in classification. When it was ambiguous whether or not a paper was eligible for inclusion (at any stage) three researchers (Professor Mike Rayner, Dr Peter

Scarborough, and me) discussed the paper and to reach an agreement. Data was extracted into an Excel spreadsheet. Where further information about a study was required the corresponding and/or the first author were contacted.

The Cochrane Risk of bias tool [71] was adapted and used to assess the study quality (Table 2.1). Studies were assessed for the following potential sources of bias; selection, performance, detection, recruitment, and funding.

Table 2.1 Risk of bias (quality) assessment: Cochrane risk assessment tool [71]

Bias domain	**Source of bias**	**Health-related claims studies**
Selection bias	a. Random sequence generation	Were participants/products randomised to the health-related claim condition?
	b. Allocation concealment	Were participants aware of claim allocation?
Performance bias	Blinding of participants and personnel	Were participants blinded to the aims of the study? (e.g. the impact of health-related claims on purchasing/consumption)
Detection bias	Blinding of outcome assessment	Were participants aware of the study outcomes?
Other bias	Anything else	How were participants recruited? Were participants/products representative of the target population? How was the study funded? Were there any conflicts of interest reported?

A two-step data analysis strategy was employed. First a sign test that indicated how the study addressed the primary research question 'do health-related claims increase, actual or intended, consumption and/or purchasing?' The second step was to quantify the effect by

calculating an odds ratio (OR) for choice-based studies and/or percentage change for consumption and/or intent-rating scale (e.g. Likert scale ratings measuring purchase or consumption intent). Studies that involved consumption as an outcome were not grouped with the choice-based studies as there are many factors that may influence whether someone chooses to consume a product, for example the time since the participant last ate, medical reasons, taste expectations and preferences etc. Where possible, 95% confidence intervals were calculated (95% CI). Where studies reported a log-likelihood for choosing a product (sometimes referred to as 'parameter estimates') the results were exponentiated to calculate the OR. Where results were presented, for the same population, for sub-types of health or nutrition claims I calculated a weighted average of the results. Parameter estimates for the entire population (i.e. not aggregated by participant characteristics) were used; where results were stratified a weighted average was calculated.

A random-effects meta-analysis was conducted due to the high level of heterogeneity between the studies. Data were analysed by claim type (health or nutrition claims) and by food category (based on UK Eatwell Guide categories [72]) which is the same food categorisation system that is used throughout this thesis. Planned analyses by participant characteristics (e.g. gender and/or socioeconomic status) were not conducted as these data were not available for the studies included for meta-analyses. An influence analysis was conducted to assess if the omission of one study would greatly alter the results of the meta-analyses. Funnel plots were conducted to assess for publication bias. The funnel plots present results for the fixed effects model as random effects models give greater weight/importance to smaller studies therefore smaller studies are more affected if there is bias present. This was discussed by Poole and Greenland, and Sterne and Harbord [73, 74].

The results presented in the papers were standardised in Excel and the meta-analyses conducted in Stata v11 SE [75].

Results

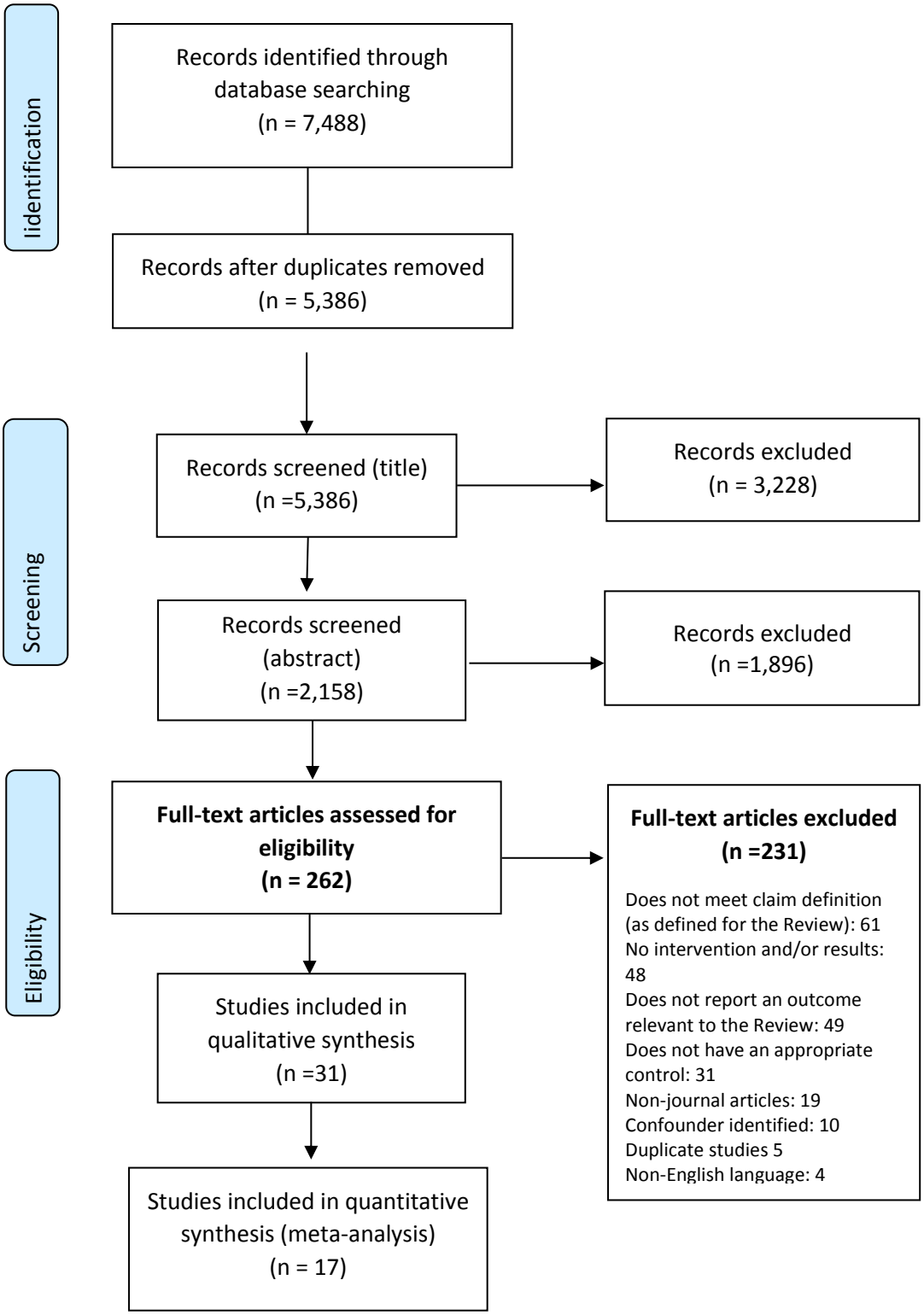
Description of studies

Results of the search

In total 5386 unique studies were identified through the database searches, of which 31 [32, 57, 76-104] were deemed eligible for inclusion. The PRISMA flow diagram is provided in Figure 2.1. The observed agreement between the two researchers on the 10% sample was 87.6% (170/194 decisions), kappa = 0.47 (95% CI 0.30, 0.65). A kappa of 0.47 would be categorised as 'moderate agreement' [105]. Of the 24 studies where there was a disagreement, only a single paper was in the final set of included studies (but not included for the meta-analyses).

Overall, 262 papers proceeded to the full paper review and their eligibility was assessed using the inclusion criteria outlined above. Following this, 231 papers were excluded. The most common reason for exclusion was that the study was not concerned with a health or nutrition claim as defined above (n=61). A summary of the 31 [32, 57, 76-104] included studies is provided in Table 2.2.

Figure 2.1 PRISMA flow diagram



Types of studies

European studies were the most common studies with four studies from Spain [81, 87-89], three from Germany [79, 80, 91], two from the Netherlands [82, 103], and single studies from Denmark [101], Greece [93], Italy [84], and the UK [85]. There were two studies that used multiple countries; Contini et al (2015, [86]) compared consumer behaviour of participants in Denmark and Italy, and Van Wezemael et al (2014, [104]) investigated consumer preferences in Belgium, France, the Netherlands, and the UK. There were eight studies [32, 57, 83, 90, 92, 96, 99, 100, 102] conducted in North America, one of which was conducted in Canada [83]. Three studies were conducted in Urguay, South America [76-78], one study was conducted in Taiwan [94], Australia [95], and two in New Zealand [97, 98].

The most common study type was choice experiments (n=15 [32, 78-81, 84, 86-89, 93, 95, 96, 98, 99, 104]), of these ten studies included conjoint analyses that were relevant to the review [32, 78, 81, 84, 86, 87, 95, 96, 98, 99]. There were nine experiments that involved participants rating, on a Likert scale, their intention to purchase or consume products [76, 77, 85, 92, 94, 97, 100-102], and six experiments that involved measuring how much participants consumed under different claim conditions [57, 82, 83, 91, 102, 103]. A single study used sales data to measure the effect of health-related claims [90].

Table 2.2 Summary of included studies

First author (year)	Country	Study design and setting	Population	Analysis
Choice experiments				
Aschemann-Witzel (2010) [79]	Germany.	Repeated measures: non-hypothetical choice/purchase simulation. Conducted in a laboratory.	220 consumers.	Chi-squared test (proportion chosen carrying claim vs overall proportion not carrying claims).
Aschemann-Witzel (2013) [80]	Germany.	Repeated measures: realistic purchase simulation. Conducted in a laboratory.	210 consumers.	One-sample T-tests: (proportion chosen carrying claim vs overall proportion not carrying claims).
De Marchi (2016) [96]	USA.	Repeated measures: price (4 levels) x calories (3 levels) x health claim (with/without) x organic claim (with/without) x carbon trust logo (with/without). Online choice experiment.	173 primary food shoppers and consumers of yogurt.	Random parameter logit with an error component model.
De-Magistris (2016) [87]	Spain.	Repeated measures: price (4 levels) x nutrient claim (absent, reduced fat claim, low salt claim). Setting unclear, conducted in-person, participants seated individually.	217 primary food shoppers.	Random Parameters Logit (RPL) model.
Fernández-Polanco (2013) [88]	Spain.	Repeated measures: price (4 levels) x origin (2 levels) x harvest method (2 levels) x sustainability (2 levels) x health claim (2 levels) x safety (2 levels).	169 participants.	Heteroscedastic logit model.
Gracia (2009)	Spain.	Repeated measures: price (2 levels) x	400 food shoppers.	Logit model.

First author (year)	Country	Study design and setting	Population	Analysis
[89]		brand (2 levels) x nutritional information panel (2 levels x claim (2 levels).		
Krystallis (2012) [93]	Greece.	Repeated measures: product type (2 levels) x claims (5 levels) x flavour (2 levels) x price (3 levels).	140 participants.	Heteroscedastic extreme value (HEV) model.
Van Wezemael (2014) [104]	Belgium, France, the Netherlands, and the UK.	Mixed design: between groups (nutrition or health & nutrition claim exposure), within group (claim, no claim) x price (4 levels). Conducted online.	2,400 beef consumers, 600 participants from; the Netherlands, Belgium, France, and the UK.	Multinomial logit (MNL) model, error component (EC) logit model.
Ares (2010) [78]	Uruguay.	Repeated measures: type of yogurt (3 levels) x brand (3 levels) x price (3 levels) x claim (with/without).	104 yogurt consumers.	Multinomial logit model (MNL). MNL used to estimate part-worth utilities.
Barreiro-Hurle (2010) [81]	Spain.	Repeated measures: price (4 levels) x nutrition label formats (2 levels) x claims (1 nutrient comparison, 1 disease reduction).	800 participants, consumers of sausages and yoghurt.	Random Parameters Logit (RPL) model.
Casini (2014) [84]	Italy.	Repeated measures: certification (4 levels) x site of production (4 levels) x health claim - (4 levels including no claim) x price (4 levels). Online survey.	260 Italian consumers.	Latent class choice model.
Contini (2015) [86]	Denmark and Italy.	Repeated measures: price (4 levels) x origin/site of production (4 levels) x health claim (8 levels -3 relevant to	2024 participants, 51% Denmark, 49% Italy.	Latent class model. Cluster analysis: 8-class model.

First author (year)	Country	Study design and setting	Population	Analysis
		Review).		
Loose (2013) [95]	Australia.	Repeated measures: 8 attributes (levels ranging from 2-8): incl. price (4 levels) and claims (3 levels). Conducted online.	1718 seafood consumers.	Scale adjusted latent class model. Aggregated multinominal logit model
McLean (2012) [98]	New Zealand.	Repeated measures: 4 factorial design: brand (3 levels) x FOP label (3 levels) x claim (3 levels) x sodium content (2 levels). Screen-based.	500 participants with hypertension, 191 participants without hypertension.	Multinominal logit regression model
Mohebalian (2012) [32]	USA.	Repeated measures: juice type (3 levels) x origin (3 levels) x health claim (2 levels) x price (continuous). Online survey.	508 participants.	Conditional logistic regression.
Mohebalian (2013) [99]	USA.	Repeated measures: fruit type x price x product origin, x health claim. Online survey.	1043 participants. Study 1: 535 participants. Study 2: 508 participants.	Conditional logit regression.
Experiments - purchase data				
Kiesel (2013) [90]	USA.	Five differentiated labelling treatments over a period of four weeks in each of five supermarkets, targeting microwave popcorn products.	Supermarket details: five treatment stores.	Summary statistics and difference-in-differences.
Experiments - measured consumption				

First author (year)	Country	Study design and setting	Population	Analysis
Roberto (2012) [102]	USA.	Randomised controlled experiment, between groups design (no label, Smart choices, a modified SC symbol with serving size). Conducted in a laboratory.	243 participants.	One-way ANOVA (continuous variables). Chi-squared tests (categorical outcomes).
Belei (2012) [82]	The Netherlands.	Randomised controlled experiment, between groups design, 3 conditions (incl. with/without claim).	109 undergraduate students.	ANOVA.
Carbonneau (2015) [83]	Canada.	Randomised controlled experiment, between groups design, 3 conditions (low fat, energy, no claim), take home meals.	160 women.	Mixed models for repeated measures used to compare impact of the experimental labelling groups on mean daily energy intake.
Koenigstorfer (2013) [91]	Germany.	Study 2: 1 factorial experiment (with claim/without) but without being made aware of perceived serving size and not observed by interviewer, conducted in a University.	Study 2: 135 students.	ANOVA.
Steenhuis (2010) [103]	The Netherlands.	Repeated measures: two conditions: with claim/without claim, 1 week washout period between. Conducted in a University.	31 female participants from the University community.	Paired sample t-tests.
Wansink (2006) [57]	USA.	Study 1: Between groups design (with claim/without), conducted during a University open day. Study 3: Between groups design (2 (regular versus low-fat label) × 3 (no	Study 1: 269 participants, students and their families visiting food science and	ANCOVAs: consumption by label type (low fat versus regular).

First author (year)	Country	Study design and setting	Population	Analysis
		serving label, “Contains 1 Serving” label, “Contains 2 Servings” label)). Conducted in a cinema.	human nutrition open day, aged 18<. Study 3: 210 university staff, undergraduates, and graduate students.	
Experiment (rating based)				
Ares (2008) [76]	Uruguay.	Repeated measures, factorial experimental design (4x4), resulting in a set of 16 food concepts.	104 participants.	ANOVA.
Ares (2009) [77]	Uruguay.	Repeated measures: three categorical factors: type of functional ingredient (2 levels) x name of the ingredient (2 levels) x claim (3 levels - No claim, ‘Enhanced function’ claim, ‘Reduced disease risk’ claim).	83 participants.	ANOVA.
Coleman (2014) [85]	UK.	Repeated measures, online survey.	122 volunteers.	ANOVA with a Bonferroni post-hoc test.
Kozup (2003) [92]	USA.	Between subjects design: 2 (heart-healthy, no claim) x3 (nutrition information level with control). Mail survey.	147 participants, primary shoppers of household.	Multivariate and univariate

First author (year)	Country	Study design and setting	Population	Analysis
Lin (2015) [94]	Taiwan.	Between subjects design: randomly assigned to with or without claim.	300 students and office workers	ANOVA.
Maubach (2014) [97]	New Zealand.	Repeated measures: 4 FOP summary indicators, x3 nutrition profile levels, x 3 product claim levels (no claim, nutrient-content, health claim), x4 flavours. Conducted online.	768 participants.	Odds ratio.
Moon (2011) [100]	USA.	Between subjects design, randomly assigned to treatment: (1) FDA permitted health claims (2) same claim without FDA approval (3) no information. Online survey.	3,456 participants.	Logistic regression, t-test.
Orquin (2015) [101]	Denmark.	Between subjects design, realistic product photographs shown 1 at a time.	Study 3: 204 participants, recruited online.	Linear regression.

Types of products and claims

There were eight studies that examined nutrition claims [57, 83, 87-90, 93, 98], 12 studies that examined health claims [32, 78, 86, 91, 92, 94-96, 99, 100, 102, 103], and 11 studies examined both health and nutrition claims [76, 77, 79-82, 84, 85, 97, 101, 104]. There was one study that measured the effects of health-related claims on 'Fruits and Vegetables' [32] whereas there were nine studies that examined 'Foods High in Fat and/or Sugar' [77, 82, 84, 86, 89-91, 93, 103], five studies examined 'Beans, Pulses, Fish, Eggs, Meat and other Proteins' [88, 95, 98, 100, 104], three studies on 'Potatoes, Bread, Rice, Pasta and Other Starchy Carbohydrates' [85, 97, 102], four studies on 'Dairy and Alternatives' [78, 87, 96, 101], and two studied ready meals [83, 92]. Six studies looked at multiple categories of foods [57, 76, 79-81, 99].

Outcomes - *Likelihood of selecting product with health-related claim*

In total, 16 studies [32, 78, 79, 81, 84, 86-89, 93, 95-99, 104] reported the likelihood of choosing a product when a health-related claim was present, one study presented the percentage chosen of products with a health-related claim [80]. These results have been transformed into odds ratio (OR) where the comparator was always the same product without any claims (Table 2.3). Meta-analyses on the 17 studies (Figure 2.2) found that products carrying health-related claims were more likely to be purchased or consumed than an identical product without a claim (OR 1.75, 95% CI 1.60, 1.91). The effect was similar for nutrition claims (OR 1.74, 95% CI 1.29, 2.35) and health claims (OR 1.73, 95% CI 1.57, 1.91). In Figure 2.2 results have been aggregated when the same claim type (health/nutrition) has been used on the same product, and on the same population.

Studies appear multiple times if results for different populations have been presented. For example, Van Wezemael (2014) presented results for health claims and, with a different population, health and nutrition claims combined, for 5 countries.

Where studies present results for the same population but multiple claim sub-types an average has been calculated. For example, Casini (2014) presented the effect of two health claims and one nutrition claim on one population. An average of the health claim was calculated and a separate value for the nutrition claim was also included.

Table 2.3 Likelihood of selecting a product with a health-related claim

First author (year)	Outcome measure	Comment	Forced choice?	Product category	Claim sub-type (nutrient/target - health relationship)	Results: OR (95% confidence intervals)	Support the hypothesis?
Ares (2010) [78]	Part-worth utilities: multinomial logit regression.	Cluster analysis. Cluster 1 more diet and health concerned than cluster 2.	Yes	Yogurt.	RDR (fibre - cancer), (antioxidants - heart disease + cancer).	C1: 1.28 (1.06, 1.56) C2: 1.38 (1.11, 1.71)	Y
Aschemann-Witzel (2010) [79]	Proportion of products that carry claims & chosen.	OR calculated from the number of choices of a product with a claim and the number of expected choices of products with a claim, if the claim was chosen at random.	No	Yogurt, muesli, pasta.	HCs: NOF (calcium + vitamin D - bones/teeth), (folic acid - mental function), (fibre - bowel function), RDR (calcium + vitamin D - osteoporosis), (folic acid - dementia), (fibre - cancer).	1.21 (0.98, 1.43)	Y
Aschemann-Witzel (2013) [80]	Percentage products with claim chosen (number of choices).	As Aschemann-Witzel (2010).	No	Yogurt, breakfast cereal, pasta.	NCs: Ncon (calcium, vitamin D), NOF (calcium, vitamin D - osteoporosis, Ncon (folic acid), NOF (folic acid - brain/mental functions).	1.10 (0.87, 1.32)	Y
Barreiro-Hurle (2010) [81]	Coefficient: random parameter logit.	Same population tested both products.	No	Pork Frankfurter sausage.	Ncon (fat) RDR (CVD) Ncon (fat) & RDR (CVD)	1.67 (1.48, 1.87) 1.97 (1.74, 2.24) 0.58 (0.49, 0.69)	Y

First author (year)	Outcome measure	Comment	Forced choice?	Product category	Claim sub-type (nutrient/target - health relationship)	Results: OR (95% confidence intervals)	Support the hypothesis?
				Yogurt.	RDR (CVD)	1.25 (1.21, 1.28)	
Casini (2014) [84]	Parameter estimates: conditional logit model.	Average of NOF and RDR used for meta-analysis as same products and population.	No	Olive oil.	NOF (polyphenols - oxidative stress) RDR (polyphenols -cholesterol) *Average* HRIC (polyphenol)	*1.44, (1.29, 1.60)** *1.23 (1.09, 1.39)** *1.33 (1.19, 1.49)* 0.88 (0.77, 1.01)	Y+N
Contini (2015) [86]	Parameter estimates: latent class model.	Average used as same product, population, and claim-sub type	No	Olive oil.	RDR (polyphenols - blood lipids) RDR (olive oil - CHD) RDR (olive oil - blood lipids) *Average*	1.41 (1.27, 1.57)* 1.66 (1.54, 1.80)* 1.70 (1.52, 1.89)* *1.58 (1.44, 1.75)*	Y
De Marchi (2016) [96]	Parameter estimates: random parameter logit with an error component.	Results adjusted for time preferences. Interaction terms not included.	No	Yogurt.	RDR (saturated fat & cholesterol - heart disease)	1.25 (1.13, 1.38)	Y
de-Magistris (2016) [87]	Parameter estimates: Random Parameters Logit model.	.	No.	Cheese.	Ncom (fat), Ncom (sodium)	2.23 (1.28, 3.87) 0.56 (0.33, 0.95)	
Fernández-Polanco	Coefficients:	Was not included	No	Fish	Ncon (omega-3)	1.63	Y

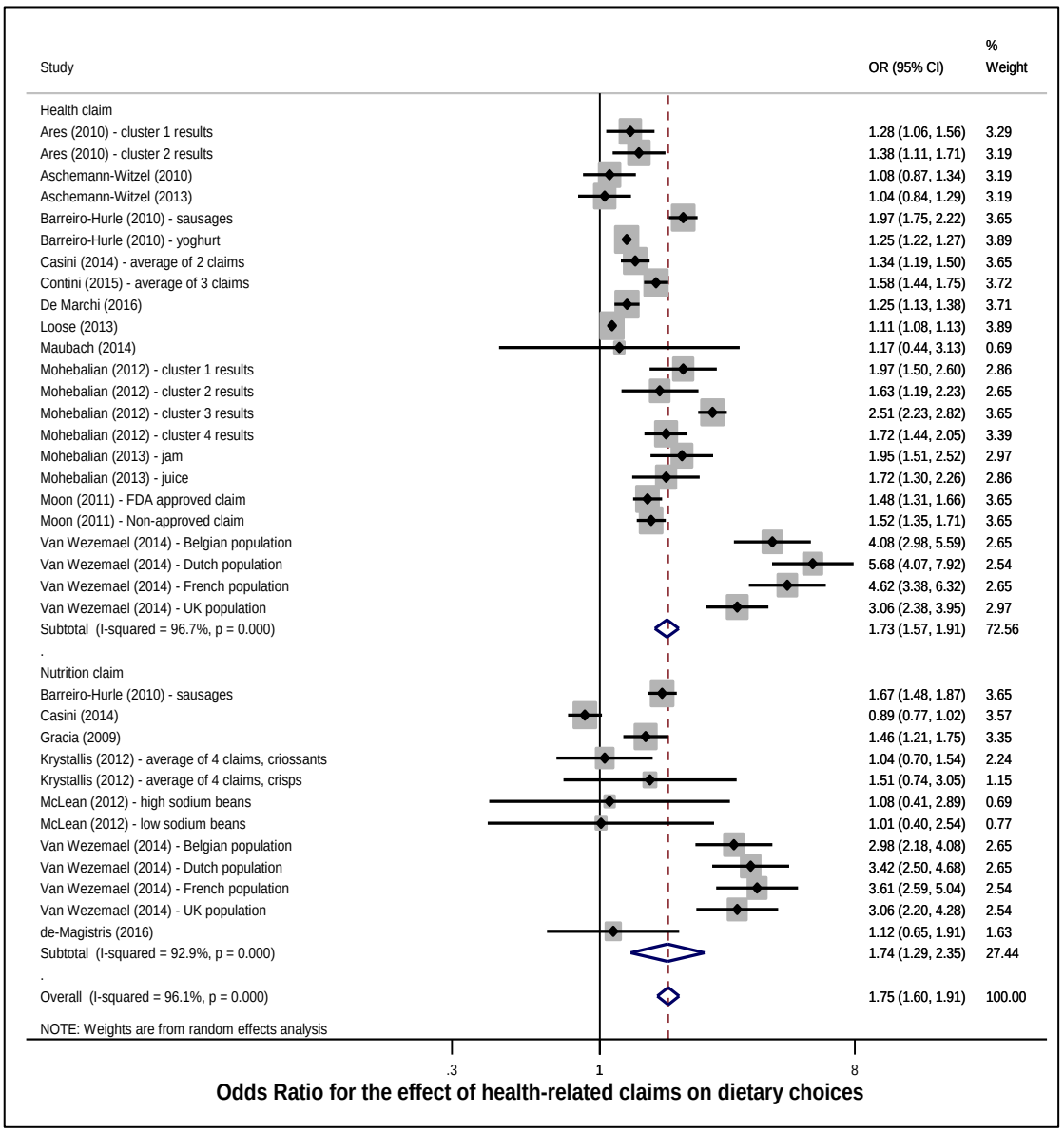
First author (year)	Outcome measure	Comment	Forced choice?	Product category	Claim sub-type (nutrient/target - health relationship)	Results: OR (95% confidence intervals)	Support the hypothesis?
(2013) [88]	conditional logit model, (+WTP).	in meta-analyses as standard error not reported.		(seabream).			
Gracia (2009) [89]	Coefficient: Parameters Logit model.	Interaction terms not included.	No	Breakfast cookies.	Ncon	1.46 (1.21, 1.75)	Y
Krystallis (2012) [93]	Coefficient (+WTP).	Averaged by product as same population and same claim sub-types.	No	Crisps.	Ncon (calcium) Ncon (vitamins) Ncon (omega-3 fatty acids) Ncon (fibres) *Average*	2.31 (1.07, 5.00)* 1.86 (0.92, 3.75)* 0.77 (0.39, 1.49)* 1.54 (0.75, 3.18)* *1.50 (0.73, 3.07)*	Y+N
				Croissant.	Ncon (calcium) Ncon (vitamins) Ncon (omega-3 fatty acids) Ncon (fibres) *Average*	1.31 (0.85, 2.00)* 1.44 (0.99, 2.09)* 0.74 (0.51, 1.07)* 0.83 (0.56, 1.22)* *1.04 (0.70, 1.53)*	
Loose (2013) [95]	Aggregated multinomial logit model/ part worth utility estimates.		No	Oysters.	Logo (Heart tick)	1.11 (1.08, 1.13)	Y

First author (year)	Outcome measure	Comment	Forced choice?	Product category	Claim sub-type (nutrient/target - health relationship)	Results: OR (95% confidence intervals)	Support the hypothesis?
Maubach (2014) [97]	Hazard ratio: binominial logit regression.	OR for health claim scaled by OR for 'no claim'. Results for NC not included. Interactions not included	Yes	Breakfast cereal.	RDR (wholegrain - cholesterol)	1.17 (1.13, 1.22)	Y
McLean (2012) [98]	Utility: multinomial logit regression (no FoP label model used)	600 participants 300 with hypertension, 300 without. Recruited from same database Averaged by product as same population and same claim sub type.	Yes	Low sodium Baked beans. High sodium baked beans.	Ncom (sodium) Ncon (sodium) *Average* Ncom (sodium)	0.66 (0.53, 0.83)* 1.55 (1.22, 1.97)* *1.11 (0.88, 1.45)* 1.21 (0.94, 1.55)	Y+N
Mohebalian (2012) [32]	Odds ratio	Cluster analysis	No	Fruit juice.	NOF (antioxidants - immune system).	C1: 1.98 (1.51, 2.59) C2: 1.63 (1.18, 2.24) C3: 2.50 (2.2.4, 2.79) C4: 1.72 (1.44, 2.06)	Y
Mohebalian (2013)	Coefficient	Different populations for	Yes	Elderberry	NOF (antioxidants - immune	1.96 (1.52, 2.52)	Y

First author (year)	Outcome measure	Comment	Forced choice?	Product category	Claim sub-type (nutrient/target - health relationship)	Results: OR (95% confidence intervals)	Support the hypothesis?
[99]		each product. Results adjusted for demographic characteristics.		jelly. Elderberry juice.	system). NOF (antioxidants - immune system).	 1.71 (1.31, 2.25)	
Moon (2011) [100]	Rating: willingness to try 5 point scale	Different populations for each claim.	No	Soy foods.	RDR (protein - heart disease) FDA approved. RDR (protein - heart disease) Not FDA approved.	1.48 (1.32, 1.66) 1.52 (1.35, 1.71)	Y
Van Wezemael (2014) [104]	Parameter estimates: error component model (best fit) (+multinomial logit model, +WTP)	Average by claim sub-type, same product, results by country.	No	Lean beef steak.	Ncon (iron), Ncon (fat), Ncon (protein). NOF (iron - cognitive function), NOF (saturated fat - cholesterol), NOF (protein - muscle).	NL: 3.42 (2.50, 4.69) BE: 2.98 (2.17, 4.10) FR: 3.61 (2.61, 5.00) UK: 3.06 (2.18, 4.30) NL: 5.68 (4.06, 7.95) BE: 4.08 (3.00, 5.56) FR: 4.60 (3.38, 6.26) UK: 3.06 (2.37, 3.97)	Y

Abbreviations: HC: Health claim. NC: Nutrient claim. HRIC: health-related ingredient claim. Ncon: nutrient content. Ncom: nutrient comparative claim. NOF: nutrient and other function. RDR: reduction disease risk. CVD: cardiovascular disease. CHD: coronary heart disease. FDA: USA Food and Drug Administration C#: cluster/class Forced choice: No = participants were able to select neither products/no buy option. Where multiple OR are given, the *OR was NOT used in the meta-analyses

Figure 2.2 Forest plot for the effect of health-related claims on dietary choices, by claim type

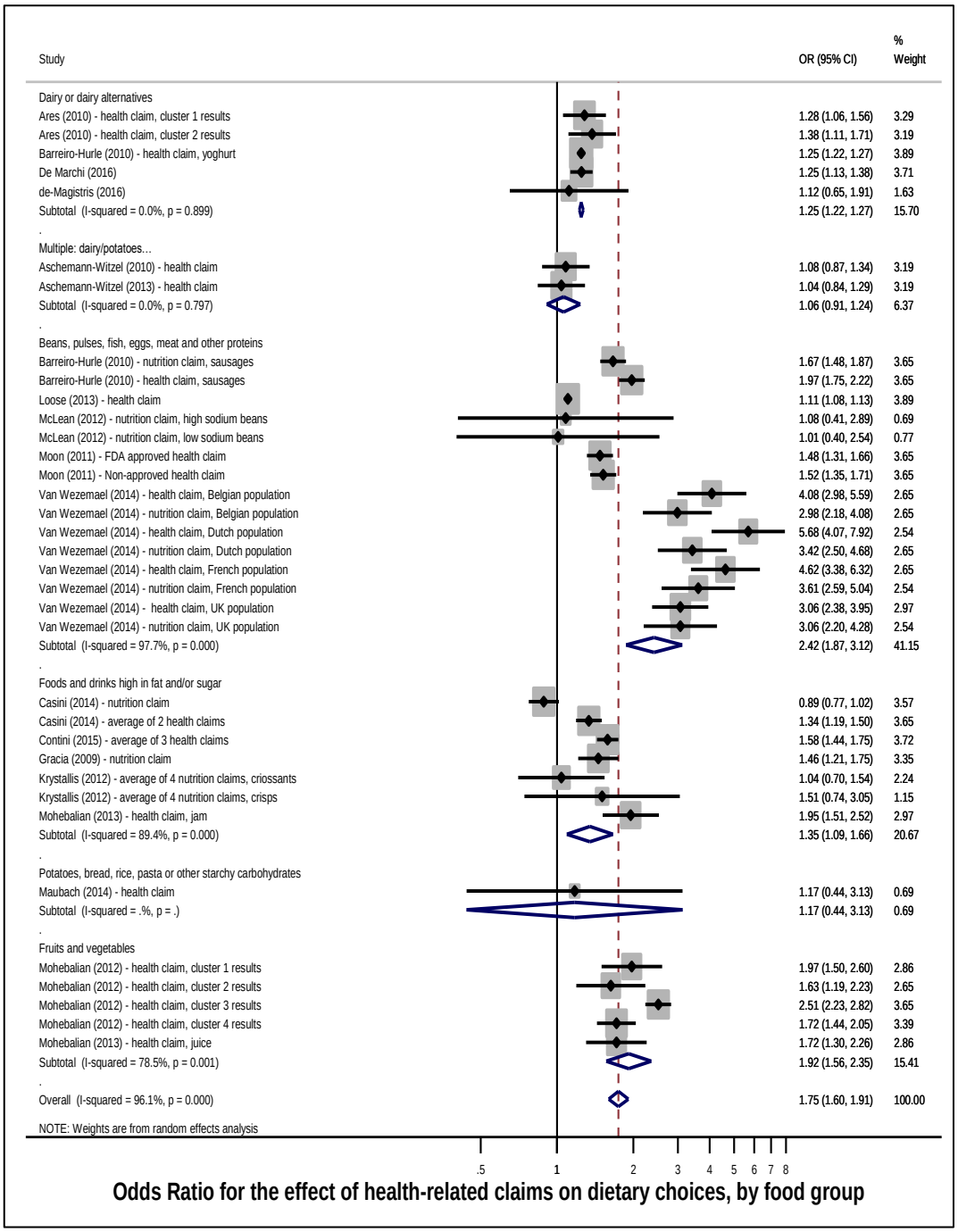


Analyses by food category (Figure 2.3) found large effects for claims on products categorised as 'Beans, Pulses, Fish, Eggs, Meat and other Proteins' (OR 2.42, 95% CI 1.87, 3.12), and 'Fruits and Vegetables' (OR 1.92, 95% CI 1.56, 2.35), moderate effects for 'Foods High in Fat and/or Sugar' (OR 1.35, 95% CI 1.09, 1.60), and 'Dairy and Alternatives' (OR 1.25, 95% CI 1.22, 1.27), modest but not-significant effects for 'Potatoes, Bread, Rice, Pasta and Other Starchy Carbohydrates' (OR 1.17, 95% CI 0.44, 3.13), and smaller, non-significant effects for multiple categories ('Dairy and Alternatives' & 'Potatoes, Bread, Rice, Pasta and Other Starchy Carbohydrates', OR 1.06, 95% CI 0.91, 1.24).

Change in preference or consumption of a product when a health-related claim was present

Products carrying health-related claims increased actual or intended purchasing /consumption by 8.9% (95% CI -4.9%, 22.6%, 10 studies) (Table 2.4). Health claims lead to a 9.8% increase (95% CI -8.4, 30.0), and nutrition claims lead to a 7.8% increase (95% CI -15.2, 30.8). The averages were then stratified by the outcome measure used. Studies that reported a rating scale outcome, such as the Coleman et al study [85] which used a 5 point rating scale of purchase intent where 1 equalled ''definitely would not buy' and 5 equalled 'definitely would buy', reported, on average, a 12.6% increase (95% CI 6.1%, 19.0%), whereas studies measuring consumption reported a 5.6% increase (95% CI -13.6%, 24.8% - five studies). A single study reporting store-level sales reported a 16.1% increase (95% CI 12.0, 20.2%).

Figure 2.3 Forest plot for the effect of health-related claims on dietary choices, by Eatwell Guide food group



The percentage change in preference/consumption differed by food groups; on average, health-related claims on 'Dairy and Alternatives' products led to a 5% reduction, whereas a 10% increase was observed for 'Potatoes, Bread, Rice, Pasta or Other Starchy Carbohydrates',

a 12% increase was observed for 'Foods High in Fat and/or Sugar', and a 7% increase for 'Composite Foods'.

A high degree of heterogeneity was observed for some of the food group analyses. This may be due to the use of different types of claims and also due to the characteristics of the food categorisation system used (the UK Eatwell Guide) for the analyses. The UK Eatwell Guide contains broad food groups, for example the group 'Beans, pulses, fish, eggs, meat and other proteins' contains one study that examined the impact of health-related claims on high and low sodium tinned baked beans and sausages (McLean, 2012 [98]) and another study that examined the impact of nutrition claims on sausages (Barreiro-Hurle, 2010 [81]).

Seven studies reported purchase/consumption intent-rating scale outcomes where a higher rating indicated a greater intention to purchase and/or consume the product [76, 77, 85, 92, 100-102], however all used different scales i.e.; 7-point [76, 77] or 5-point [100] willing to try scales or, 5-point [85], 7-point [92, 101], or 9-point purchase intent scales [102]. Five of these studies reported increases in intent when a health-related claim was present [77, 85, 92, 100, 102] ranging from +1% [85] to +52% [100]. Coleman [85] tested five types of health claims on white bread and found that some claim types had a stronger effect than others. For example a nutrient and other function claim related to satiety led to a 1% intent increase (non-significant) whereas a similar nutrient and other function claim related to mineral content led to a 22% intent increase (95% CI 15%, 29%). Ares [76] found a reduction in intent when health and nutrition claims were presented on yogurts, desserts, bread and mayonnaise.

Five studies [57, 82, 83, 91, 103] reported the mean amount of food consumed in different health-related claim scenarios. Belei, Geyskens, Goukens, Ramanathan, & Lemmink (2012) [82], Koenigstorfer, Groeppel-Klein, Kettenbaum, & Klicker (2013) [91], Steenhuis, Kroeze, Vyth, Valk, Verbauwen, & Seidell (2010) [103], and Wansink & Chandon (2006) [57] all measured the mean amount (in weight) of food consumed, whereas Carbonneau et al (2015)

[83] measured the mean nutrient intake over a ten day period. Despite reporting similar outcome measures there was still considerable variance in the in the average food consumption in the five studies. For example, when nutrition claims were present there was a 3-4% increase in consumption of ready meals [83] and a 28-50% increase in chocolate consumption [57], but a 149% increase in consumption of trail mix when a health claim was present [91]. Steenhuis et al (2010) [103] examined the effect of the Choices health logo [106] on a chocolate dessert and found a 7% reduction (not statistically significant) in consumption. Belei et al (2012) [82] also studied the effects of health-related claims on a chocolate product and found that a 38% increase in consumption when a nutrition claim was present and a 34% reduction when a health claim was present. Belei et al then replicated this study and had similar results for the effect of a nutrition claim (43% increase) and found a larger reduction when a health claim related to antioxidants was present (-47%), and an even larger reduction with a low cholesterol claim (-50%).

In two studies Aschemann-Witzel et al [79, 80] reported the proportion of products with a health-related claim that were chosen from a selection of products and found a 2-5% increase in the number of choices of products than if products were chosen at random.

Risk of bias

The risk of bias table is available in Appendix B. In total, 13 studies were identified as being at risk of selection bias due to the use of research panels for recruitment [32, 85, 87, 92, 93, 95-101, 104], and for four studies the method of recruitment was not clear [79, 82, 86, 89]. For studies involving participants, most used random allocation and/or random sequence generation. The majority of the studies were at risk of performance bias as just three studies [57, 83, 101] used cover stories to reduce demand characteristics. For example, Wansink & Chandon (2006) [57] compared the amount of granola consumed when it was labelled as 'low

fat’ to when it was labelled as ‘regular’ but informed participants that the purpose of the study was to rate a video to reduce the likelihood that participants would alter their behaviour in accordance to the study aims.

Table 2.4 Change in preference or consumption of a product when a health-related claim was present

First author (year)	Outcome measure	Product category	Claim sub-type (nutrient/target - health relationship)	Results	Does it support the hypothesis?
Ares (2008) [76]	Rating: willingness to try, 7-point Likert scale	Yogurt	NOF (antioxidants) Ncon (fibre) Ncon (fat)	-3.8% (-5.9%, -1.6%) -3.3% (-5.5%, -1.2%) -6.8% (-8.9%), (-4.7%)	Y+N
		Milk desserts	NOF (antioxidants) Ncon (fibre) Ncon (fat)	-3.0% (-5.2%, -0.8%) -2.8% (-5.0%, -1.0%) -1.81% (-4.0%, 0.4%)	
		Bread	NOF (antioxidants) Ncon (fibre) Ncon (fat)	-4.0% (-6.3%, -1.7%) -0.7% (-3.0%, 1.6%) -4.2% (-6.5%, -1.9%)	
		Mayonnaise	NOF (antioxidants) Ncon (fibre) Ncon (fat)	-12.1% (-14.6, -9.6) -19.9% (-22.37, -17.34) -1.01% (-3.5%, 1.5%)	
Ares (2009) [77]	Rating: willingness to try, 7-point Likert scale	Milk dessert	NOF (fibre - calcium absorption + beneficial gut bacteria),(antioxidant - fat oxidation + cellular health) RDR: (fibre - cancer), (antioxidants - heart disease + cancer) Ncon (fibre, b-glucans, Ncon (antioxidant, flavoids)	+29.4% +31.5% +16.3% +14.1%	HC: Y NC: N
Belei (2012) [82]	Mean amount consumed	Chocolate	Ncon (fat) NOF (cacao - antioxidant) Replication study: Ncon (fat)	+38.4% (25.0%, 51.7%) -34.3% (-41.3%, -27.3%) +43.4% (18.5%, 68.2%)	Y+N

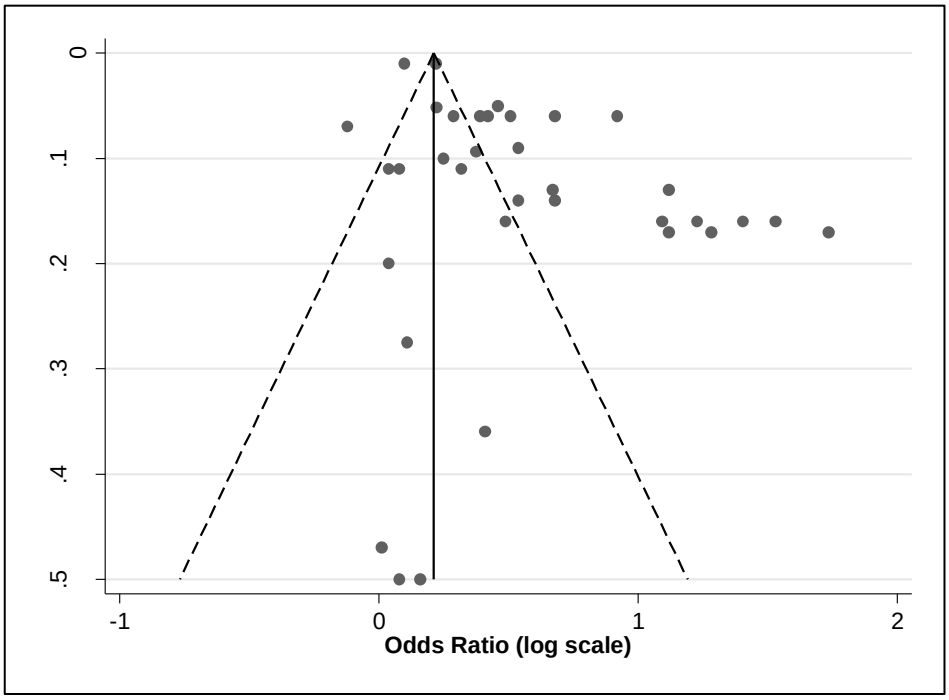
First author (year)	Outcome measure	Product category	Claim sub-type (nutrient/target - health relationship)	Results	Does it support the hypothesis?
			NOF (cacao - antioxidant) Ncon (low cholesterol	-47.2% (-54.4%, -39.9%) -49.5% (-54.6%, -44.4%)	
Carbonneau (2015) [83]	10 day mean energy (kcal) intake	.	Ncon (fat) Ncon (energy)	+3.4% (-2.1%, 8.9%) +3.9% (-1.9, 9.8%)	Y
Coleman (2014) [85]	Rating: purchase intent, 5-point Likert scale	White bread.	HRIC or GHC/Prebiotic NOF (Satiety) NOF (weight) RDR (cancer) NOF (minerals)	+17.6% (11.2%, 24.0%) +1.2% (-5.7%, 8.1%) +14.9% (6.4%, 23.4%) +13.3% (5.3%, 21.4%) +22.0% (15.1%, 28.9%)	Y
Kiesel (2013) [90]	Sales over 4 weeks for pre-exposure and exposure period.	Microwave popcorn.	NUTRIENT CLAIMS Ncon (energy) Ncon (fat) Ncon (fat –FDA)	+16.1% (12.0%, 20.2%) +25.4% 14.6% +3.2%	Y
Koenigstorfer (2013) [91]	Mean amount consumed N serving themselves:	Savoury snack (trail mix)	GHC (Fitness)	+149% (110.9%, 186.2%) OR 4.4 (3.6, 5.1)	Y
Kozup (2003) [92]	Rating: purchase intent, 7-point Likert scale	Frozen ready meal (lasagne)	RDR (saturated fat + cholesterol - CHD), Logo (Heart healthy - novel logo with description provided)	15%	Y
Lin (2015)[94]	Purchase intent rating	Tea drink	NOF (weight loss)	+10.22% (-20.9%, 41.4%)	Y
Roberto (2012) [102]	Rating: purchase intent, 9-point Likert scale	Breakfast cereal	Logo: Servings per pack Logo: Serving size	+16.3% (-2.7%, 35.4%) +23.7% (3.8%, 43.6%)	Y + N

First author (year)	Outcome measure	Product category	Claim sub-type (nutrient/target - health relationship)	Results	Does it support the hypothesis?
	Meant amount consumed: Total cereal + milk eaten (grams) Cereal poured (grams)		Buying for children Logo: Servings per pack Logo: Serving size Logo: Servings per pack Logo: Serving size	+ 20.4% (0.8%, 40.1%) +16.6% (-2.3%, 35.4%) -0.3% (-13.9%, 13.3%) +5.8% (-9.4%, 21.0%)	
Steenhuis (2010) [103]	Mean amount consumed	Chocolate mousse cake	Logo (Choices)	-7.4% (-21.7%, 6.9%)	N
Wansink (2006) [57]	Study 1: mean calories served Study 3: mean calories consumed	Chocolate and granola.	Ncon (fat)	Study 1: +28.4% Study 3: +50.1%	Y

The target population was often not stated in the paper; however 10 studies [32, 78, 80, 81, 86, 88, 89, 99, 100, 104] found that their participants' characteristics fit well with national census data. No studies explicitly listed any conflicts of interest due to industry funding.

Tests revealed a high level of heterogeneity in the results (I-squared: overall 96%, health claims 97%, nutrition claims - 93%). A funnel plot showed strong asymmetry suggesting that there was publication bias (Figure 2.4).

Figure 2.4 Funnel plot for publication bias (with pseudo 95% confidence limits)



An influence analysis was conducted to assess if the omission of one study would greatly alter the results of the meta-analyses. Overall, four studies had a large effect on the results, the omission of which affected the estimated effect size by more than 5%. When the Van Wezemael et al study [104] was omitted it led to an 18% reduction to the overall estimated effect size (OR 1.43, 95% CI 132, 1.55), the omission had a greater impact on the effect size for

nutrition claims (30% reduction, OR 1.22, 95% CI 0.93, 1.60) than for health claims (18% reduction, OR 1.49, 95% CI 1.36, 1.62). Three other studies also led to greater than 5% change in the estimated effect size for nutrition claims - omitting Casini et al (2014) [84] led to a 10% increase (OR 1.91, 95% CI 1.47, 2.48), whereas omitting Krystallis & Chrysochou (2012) [93] and Mclean, Hoek, & Hedderley (2012) [98] led to smaller increases (OR 1.85, 1.33-2.59, and OR 1.84, 95% CI 1.34, 2.54, respectively).

Discussion

Summary of main results

Results of choice experiments (without actual purchasing of foods) suggest that products carrying a health-related claim are 75% more likely to be chosen than an identical product without a health-related claim (OR 1.75, 95% CI 1.60, 1.91). This effect is similar for nutrition claims (OR 1.74, 95% CI 1.29, 2.35) and health claims (OR 1.73, 95% CI 1.57, 1.91). The effect varies by the category of the food that the claim was presented on: larger effects were seen for health-related claims on products categorised as 'Beans, Pulses, Fish, Eggs, Meat and other Proteins' (OR 2.42, 95% CI 1.87, 3.12) or 'Fruits and Vegetables' (OR 1.92, 95% CI 1.56, 2.35), than for 'Foods High in Fat and/or Sugar' (OR 1.35, 95% CI 1.09, 1.60) or other food categories.

The results should be viewed with caution due to the risk of bias associated with the studies, the high degree of heterogeneity in study findings and the potential risk of publication bias revealed by the funnel plot. Overall, the results that have been derived from studies using continuous outcomes (ratings, sales, amount consumed etc.) demonstrate much more conservative results than those that have been estimated by conjoint analyses. Averages of such studies estimated that health-related claims led to just an 8.9% (95% CI -4.9%, 22.6%) increase in purchases/consumptions. Kiesel & Villas-Boas (2013) [90] examined the effect of

nutrition claims (on shelf labels) on real-life purchases of popcorn products by examining, across five stores, the difference in sales between when a shelf-label intervention was present and when it was not. They found that low calorie claims increased sales but low fat labels decreased sales. When these results were standardised for this systematic review I estimated the overall effect of nutrition claims to increase sales by 16.1% (95% CI 12.0, 20.2), much lower than 75% increase for nutrition claims estimated from the meta-analyses by claim type, and closer to the 35% increase for Foods high in fat and/or sugar estimated from the meta-analyses by food group (OR 1.35, 95% CI 1.09, 1.66, 7 studies).

The results from the meta-analyses suggest that health and nutrition claims have a similar effect on dietary choices. This would be supported by previous research on health-related claims which suggests that consumers often do not clearly distinguish between health and nutrition claims [52].

The studies included in this systematic review cover a range of foods and all of the food groups (as categorised by the UK Eatwell Guide) were represented, however there was only one study [32] that examined the effect of health-related claims on fruits and vegetables. Mohelbalian, Cernusca, & Aguilar (2012) conducted a choice experiment examining health claims on a fruit juice product and found that the odds of choosing the product with a health claim varied by how health conscious the consumer was and whether they already consumed the product. Less health-conscious consumers who already consumed the fruit juice were more likely to choose the product with the health claim (OR 1.63, 95% CI 1.19, 2.23) but health-conscious consumers who did not already consume the product had a much higher odds of choosing the product when a health claim was present (OR 2.51, 95% CI 2.23, 2.82). This suggests that consumer attributes, such as lifestyle traits, may be an important mediator of the effect of health-related claims.

Although each data line in the meta-analysis is drawn from either a separate experiment or a separate population (or both) many were conducted with similar methods and hence potentially similar biases (e.g. Van Wezemael, 2014 [104]). In the random effects models that I used in this paper I did not adjust for potential correlation between estimates produced with similar methods. In a multilevel meta-analysis (35 results nested in 17 studies) of the combined effect of health and nutrition claims the effect size reduced from 1.75 to 1.41 (95% CI 1.20, 1.67). Such a method accounts for study-level correlation [107], however in this case may over-adjust since the data lines are all drawn from either separate experiments or separate populations or both.

Whilst choice experiments are able to isolate the effect of the claim from other competing influences (e.g. price, brand, store factors etc.), they are conducted in an artificial context and therefore may have limited external validity. Similarly, in these choice experiments participants are asked to choose between the product with a claim and the control product (without a claim). It is unclear whether these choices would equally translate into real-world purchases made with the participants' own money, particularly when other factors such as positioning, package design, and brand factors are likely to play a role.

The 75% boost in sales/consumption was derived from the meta-analyses of choice experiments where the participant was asked to choose between a product with a health-related claim and an identical product without a health-related claim. As such, these types of studies do not consider the overall prevalence of foods with health-related claims. It's possible that if there was a high prevalence of health-related claims that the impact of the presence of a health-related claim on a food would be lessened. One potential method to investigate this would be to measure the impact of health-related claims in stores/settings with different health-related claim prevalence – for example measuring sales of a product with a 'low fat'

claim in multiple stores where the prevalence of health-related claims differed. However, I'm not aware of any studies that have examined this.

Implications for this thesis

The finding that the effect of health-related claim differs, often substantially, between food groups identifies the need to take food group into account when presenting results. For example stratifying the prevalence rates (the proportion of foods that carry a claim) by food group (as done in Chapter 4) and/or where appropriate adjusting for food group, for example in Chapter 5 I conduct a regression analysis for the mean levels of nutrients for foods that carry health-related claims and foods that do not. Food group is a potential confounder for the differences in nutritional quality of foods carrying health-related claims and foods not carrying health-related claims (i.e. certain food groups may be more likely to carry claims than others, and some food groups may have higher or lower levels or nutrients), it is therefore important to adjust for food group in the analyses.

The finding that health claims and nutrition claims affect dietary choices by the same amount (nutrition claims OR 1.74, 95% CI 1.29, 2.35, and health claims OR 1.73, 95% CI 1.57, 1.91) suggests that there may not be a need to differentiate between the two types of claims in later chapters.

Limitations of the review

This systematic review is the first, that I am aware of, that has attempted to quantify the effect of health-related claims on dietary choices using odds ratios and/or estimating the percentage change in consumption, willingness to purchase/consume, or actual sales. I have

used an established taxonomy for the classification of claims which is compatible with EU and international regulations.

As there has been a large amount of research published on various aspects of health-related claims (e.g. claim understanding, substantiation, recognition etc.), during the abstract screening stage studies were only included if the abstract mentioned one of the following outcomes; choices, purchases, or consumption. It is possible that studies that did not mention an outcome relevant to the systematic review went on to present relevant results in the full paper – such studies would not have been included.

Furthermore, a single researcher conducted the screening and data extraction. However, I attempted to limit the potential bias of this through conducting a 10% title check and then at the abstract screening stage all three reviewers discussed the excluded and 'undecided' papers.

Conclusions

Findings from discrete choice experiments suggest that health-related claims have a substantial effect on dietary choices; however this effect varies according to the type of product. Further research is needed to see whether results may be replicated with similar claims and products. Furthermore, studies conducted in more natural settings suggest that health-related claims play a much smaller role in real-life dietary choices. This review highlights the need for more research into the effect of health-related claims on real-life dietary choices.

Further work is also required to establish whether health-related claims lead to changes in dietary choices between products within a category (e.g. switching a cola drink for a fruit juice), or whether they increase total purchasing/consumption within a food category.

After taking these considerations and the findings of this review into account, it appears that health-related claims are likely to have a large effect on purchasing and consumption and, thus in turn, on public health. However, this effect will be moderated by both the prevalence of health-related claims (Chapter 4) and whether the foods carrying health-related claims have a more favourable nutritional composition than foods that do not carry health-related claims (Chapter 5).

3. Methods

Introduction

In this chapter I describe the methods used to answer the following research questions:

1. What is the prevalence of health-related claims in the UK, Germany, the Netherlands, Spain, and Slovenia (Chapter 4)?
2. Do foods that carry health-related claims have a better nutritional composition than foods that do not (Chapter 5)?
3. What would be the impact of using different nutrient profile models to regulate health-related claims in terms of claim prevalence and nutritional composition (Chapter 6)?
4. What is the (current) effect of health-related claims on health outcomes in the UK, and what would be the impact of using a nutrient profile model to regulate health-related claims (Chapter 7)?

In this chapter I also describe my role in the team that compiled the database necessary for the analyses described in Chapters 4 - 7.

Compilation of a database of foods with and without health-related claims

Some of the data for this thesis were collected as part of the CLYMBOL ('Role of health-related CLaims and sYMBOLs in consumer behaviour') project.

The CLYMBOL project

The CLYMBOL project was a four year project that ran from 2012 to 2016. The project was funded by the European Commission under the Food, Agriculture and Fisheries, and

Biotechnology theme of the 7th Framework Programme for Research and Technological Development.

The project was co-ordinated by Dr Sophie Hieke from The European Food Information Council (EUFIC) and involved 14 collaborators, including the University of Oxford, from nine countries in Europe. The overall project aim was to understand how health-related claims influence consumer behaviour.

The project consisted of seven work packages, five of which were related to research tasks (work packages 1-5), and two work packages were related to either research dissemination (work package 6) or project management (work package 7). Each of the five main work packages was divided into research tasks and for each research task a deliverable report was submitted to the European Commission as per funding requirements. The data used in this thesis were produced under work packages 1 & 2, for details on the remaining work packages and tasks see Hieke et al 2015 [108].

The University of Oxford researchers who worked on the project were Professor Mike Rayner, Dr Peter Scarborough, and me. Below is a description of the CLYMBOL tasks related to this thesis, including my role in carrying out the tasks, the methods used in each task are discussed in greater detail in the following section.

Work Package 1, task 1.3: Prevalence of health-related claims

The aim of this task was to estimate the prevalence of health-related claims in five EU countries (Germany, the Netherlands, Spain, Slovenia, and the UK). The task leader was Dr Hieke from EUFIC and the University of Oxford team were task partners. I, with support from Prof Rayner and Dr Scarborough, was responsible for developing the sampling methods and materials. I drafted a data sampling and data extraction protocol which I then piloted in a local store in Oxfordshire. An additional piloting stage was also conducted by Saarland University in

a large supermarket in Germany. Following this Dr Hieke added further components to the protocol to capture data required for other tasks with which the Oxford team was not involved. Dr Hieke co-ordinated the research groups responsible for data collection and circulated the materials used (Appendix C).

The following research groups were responsible for collecting and extracting data:

- University of Surrey, UK
- University Wageningen, Netherlands
- Saarland University, Germany
- University of Ljubljana, Slovenia
- Agrifood Research and Technology Centre of Aragon, Spain

Using the database templates provided, the local researchers collected and extracted the data and then sent the completed databases to me for cleaning and analyses. The first step was to standardise and clean each of the five databases so that I could merge them into one master dataset.

I conducted most of the analyses used for the deliverable report and for the publication that resulted from this task and conducted all of the analyses on the data that are presented in this thesis.

To date, two main publications have been published that report analyses that used these data. The first was a cross-sectional survey estimating the prevalence of health-related claims in Germany, the Netherlands, Spain, Slovenia, and the UK [109], I produced the tables for this paper and assisted Prof Rayner in writing the 'Results' section of the paper. The second paper is discussed below.

Work Package 1, task 1.4: Analyses of the nutritional composition of foods carrying health-related claims.

The University of Oxford was the leader of this task. This task used the data collected in the previous task to compare the mean levels of nutrients of foods carrying health-related claims with foods that do not. I conducted all of the analyses for this task and assisted Prof Rayner with the writing of the Deliverable Report for the European Commission. I also wrote a paper comparing the mean levels of nutrients in foods with and without health-related claims [110].

Work Package 1, task 1.5: A comparative analysis of the nutritional criteria for health-related symbols.

The University of Oxford was the leader of this task. This task used the same database of foods from five EU countries to compare the strictness of six nutrient profile models, three of which are used (or proposed for use) for the regulation of health-related claims and three which are used as nutritional criteria to decide whether a food is eligible to carry a health symbol. I conducted the analyses and assisted Dr Scarborough with writing the Deliverable Report. The analyses presented in this thesis were conducted by me using the finalised database. There is a paper planned based upon Chapter 6.

Work Package 2, task 2.2b: Modelling the impact of health-related claim on health outcomes

The University of Oxford was the only research group involved in this task. The task consists of a systematic review of the impact of health-related claims on dietary choices and then a modelling exercise to estimate the effect of health-related claims on UK mortality rates. I am the lead author of the systematic review which was published in the International Journal of Behavioral Nutrition and Physical Activity [63]. This task uses the estimates for the prevalence of health-related claims (task 1.3) and estimates for the nutritional quality of foods carrying health-related claims (task 1.4). I wrote the deliverable report of the modelling exercise with

support from Prof Rayner and Dr Scarborough. Since then I have conducted analyses which are presented in Chapter 7. This study shall also be written up as a paper.

The prevalence of health-related claims (Chapter 4)

The prevalence of health-related claims in Europe had not previously been estimated by using a random selection of food products, across all food categories, available to purchase in Europe. Here, 'prevalence' refers to the proportion of foods that carry health-related claims on its packaging and 'foods' refers to pre-packaged foods (and beverages) available to purchase in food stores.

Previous estimates of the prevalence of health-related claims typically focussed either on a small number of food categories [28], foods that are commonly consumed [111], or were audits of the types of health-related claims currently present on food labels [112]. The sampling of foods in five EU countries was based on a pre-determined protocol (see Appendix C). The aim of the protocol was to sample randomly from a pre-defined population of foods in order to produce a sample representative of packaged foods available for purchasing in Germany, the Netherlands, Spain, Slovenia, and the UK. A summary of the methods used is provided below.

Population

Products were eligible to be sampled if they were pre-packaged foods or non-alcoholic beverages intended for human consumption. Alcoholic beverages were excluded as the rules for claims on these foods differ.

The European Commission defines a 'pre-packaged foodstuff' as:

"any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging." (page 23, Article 1, Directive 2000/13 [25])."

Products that were available in a number of variations of sizes and packaging were considered as different products as they may differ in space available for different claims, for example a 330ml can, a 500ml bottle, and a 1 litre bottle of cola would be considered as three different/unique products.

Sampling

Once the population of foods was defined, the next step was to estimate the size of the sample that would be needed for this project, and then to develop a random sampling frame to ensure that the selected foods are representative of the population of foods described above.

A power calculation was conducted with various sample sizes to estimate the precision of potential results. After taking time and budget constraints into account a sample size of 400 foods per country was used which would produce confidence levels of +/-5%, thus a 10% difference in the prevalence of claims between countries would be detected.

Sampling frame

The 14 CLYMBOL collaborators were based across ten European countries. Five countries, Germany, the Netherlands, Spain, Slovenia, and the UK, were chosen for data collection due to the experience and availability of the researchers.

Products were sampled from three different store types to reflect the different types of retail settings that consumers tend to use. A similar approach was used in the Food Labelling to

Advance Better Education for Life (FLABEL) project [28]. In each country 250 products (63%) were sampled from a large supermarket or a national retailer, 75 products (19%) were sampled from a Discounter store and 75 products (19%) from a neighbourhood store. A greater proportion of foods was sampled in supermarkets as, for most households, the majority of food purchases are made here [113, 114].

The following definitions of store types were used:

"Large supermarket / national retailer: a store (close to the location of the partner in charge) of a chain with high national market share. Additional characteristics include a comparable size (square metres) and similar day/time of data collection across the five countries.

Discounter: a store (close to the location of the partner in charge) of the discounter with high national market share. Additional characteristics include a limited range of products, a high proportion of private labels within the assortment and limited service (often: self-service) in-store. As per definition, selling space of a discounter must not exceed 1,000 m2. Day and time of data collection must be comparable across the five countries.

Neighbourhood store: a store (close to the location of the partner in charge) with a sales area of 400 – 800 m2 and a product range of 7,000 – 12,000 items. The percentage of non-food items must not exceed 25%. Additional characteristics include a high national prevalence of the chain selected and similar day/time of data collection across the five countries."

(page 7, [115])

A number of factors influenced which retailer and the exact store chosen to sample from. Initially, the retailer to be sampled in each country was to be decided on the basis of who had the biggest market share in each country. However, this wasn't consistently feasible due to sales data not always being readily available and where it was available the retailer with the leading market share may not have had stores in close proximity to the data collectors. As permission was sought by the retailers this also influenced the choice of store as several stores declined to participate. Finally, the location of the store played an important role as several visits were required.

It was then necessary to devise a method to sample foods from the identified stores on a random basis. Two methods were used for sampling products:

1. Store list method

This was the preferred method as it was deemed the easiest to replicate whilst also being efficient uses of limited resources. Stores that had agreed to allow data collection were asked to provide a stock list of products available to purchase within the given store. Stock lists were provided in various electronic formats (e.g. an Excel file or a pdf.) and some lists were only provided as hard copies. The products in the list were usually grouped into the retailers' own product categories. Where possible, the irrelevant product categories were excluded at this stage (e.g. non-food categories such as laundry products etc.). Product categories that may include a small number of non-food items, such as birthday candles often found in the baking aisle/category in stores, were not excluded. If a non-food item was sampled then a new randomly selected product was chosen as a replacement. The remaining eligible categories were assigned an identification number and the products within each category were consecutively numbered. An Excel spreadsheet was used to generate random numbers using the 'RAND' function. The numbers were weighted by the number of products within a category and the number of products within the store so that every product within the eligible categories had an equal chance of being selected. If a product randomly sampled from a store list was unavailable to purchase on the day of data collection, a new randomly selected product was chosen.

2. Store floor plan method

This method was employed when the store list was not available or was not deemed to be accurate. The first step was to create a floor plan of the store. The floor plan would detail the general layout of the store including a description of what type of products were available on each aisle, promotional displays and any other areas where products were displayed. Each section was then assigned an identification number along with an estimate of the number of

unique products in that section. This effectively assigns each unique product within a given section an ID number that runs consecutively from the start of the section to the end of the section. Data collectors were required to use a tally counter and count the number of unique products within two aisles and estimates were then based upon this number. Other areas such as end of aisle displays were counted separately. Where feasible, particularly in smaller stores, data collectors were asked to count the number of products using the tally counter rather than making estimates. This was due to the smaller stores and discounters tending to have a less homogenous layout thus no aisle could be deemed typical.

Data collectors were advised to be liberal with their estimates as by underestimating the number of products in a section some products will be inadvertently excluded from the sampling frame. This may lead to systematic bias as there is research that suggests that less healthy products may be found at the end of the aisle [116]. To account for this the data collectors were instructed to alternate the direction in which they counted through the products in each aisle. The full instructions given to data collectors can be seen in Appendix C and Appendix D.

The floor plan and the estimates of product numbers were used to generate unique ID numbers for all food products in a store. A random sample of ID numbers was selected in the same way as above, and researchers were sent to the stores to purchase the randomly sampled product numbers. For example, if store section 4, product 65 was randomly sampled, then the researcher would go to store section 4 (as indicated on the floor plan) and purchase the 65^{th} product encountered using a standardised product counting method. Random sampling of the store sections was weighted to account for the different number of products in different sections, so that each food product in the store had an equal chance of being sampled.

If the number of products within a section had been over-estimated then it is possible that a random number generated did not represent an actual product (for example if the 80th product was selected from a section that only has 70 products). In these instances a new section and product number was randomly selected.

Table 3.1 presents the stores used for data collection, the data collection method, and the number of products purchased. The store list method was employed for all three store types in the Netherlands, Slovenia, and Spain. For data collection in the UK the floor plan method was used for all three store types. Both data collection methods were used in Germany.

Table 3.1. Data collection summary: sampling method and store type

	UK	**Netherlands**	**Germany**	**Slovenia**	**Spain**	**Total**
Large supermarket/ national retailer	Floor plan n=248	Store list n=252	Store list n=248	Store list n=260	Store list n=251	1,259 (62%)
Discounter	Floor plan n=75	Store list n=81	Store list n=76	Store list n=78	Store list n=78	388 (19%)
Neighbourhood store	Floor plan n=75	Store list n=83	Floor plan n=75	Store list n=78	Store list n=76	387 (19%)
Total number of products purchased	**398 (20%)**	**416 (20%)**	**399 (20%)**	**416 (20%)**	**405 (20%)**	**2034 (100%)**

Pilot studies

During the development of the floor plan method I conducted a small pilot study to identify any potential problems that may occur during data collection. The pilot study took place in January 2013 in a small neighbourhood shop in Oxfordshire. Using the floor plan method 25 products were randomly sampled from 1,104 eligible products available to buy within the

store. In order to check the accuracy of the estimates of the number of products in each section I then counted the number of products within the store using a tally counter. I then used a random number generator app available on a smart phone to select 25 products. The data collection took approximately half a day to complete.

Two changes were made to the protocol following the pilot study. Firstly, data collectors were now encouraged to count the number of products in smaller stores rather than making estimates. This was due to the data collection taking less time than originally anticipated but also due to the tendency to over-estimate the number of products. Secondly, a random number generator was created in Excel which produced a list of section numbers and product IDs. The data collectors then used this list and the store map to find the products in store. Generating the numbers in this way meant that the generated list could be sorted by section and product ID so that finding the products would only involve counting down each aisle once.

The protocol was then piloted again, this time with the Excel spreadsheet, in a large store in Germany but no further changes were made.

Data extraction

The food labels of all of the purchased food products were retained for data extraction. We extracted the product details, selected ingredient declarations, nutritional information, and claim information. The data was collected and extracted by researchers within each country.

The following methods were applied to all products regardless of the sampling method employed.

The randomly selected products were purchased and the packaging was carefully removed and stored for data extraction. Each product within each country was then assigned an ID number. Photographs were taken of products carrying at least one claim. To avoid food

wastage researchers were encouraged to either donate food to local charities or make the food (minus the packaging) available to staff members to consume.

A data extraction protocol and database was circulated to all researchers (Appendix C). The data were recorded in an Excel spreadsheet. Where appropriate, drop-down menus were used in order to amalgamate responses and reduce the risk of data entry errors. Free text fields were used sparingly to avoid translation issues due to the different languages used in each country. The first section of the spreadsheet collected details relating to the product collection, e.g. the country of data collection, the store type and the price of the product). The product name was written as appears on the packet including the size (e.g. "WEIGHT WATCHERS FROM HEINZ, BAKED BEANS IN TOMATO SAUCE, 200G"). The presence of various indicators of nutritional content was recorded in a binary fashion, for example whether the product contained any nutrient declarations, or nutrient specific systems (e.g. traffic light labelling) or an ingredient list. This was largely due to many nutritional indicators and/or statements being so ubiquitous recording them in this format would be the most time efficient.

Products were categorised into a food categorisation devised by another study which also sampled pre-packaged foods [117]. The Dunford et al (2012) paper promotes standardised methods and food categorisations for surveys of processed foods in different countries. The food categorisation system contains 15 food groups (e.g. "Beverages", "Bread & bakery products", "Cereal & Cereal Products" etc." Most of the food groups are broken down into smaller food categories, in total there are 50 food categories (Appendix E).

Products were also categorised into the groups used for each nutrient profile model (discussed further in Chapter 6). For the analyses presented in this thesis I re-categorised the foods into the five groups used in the UK Eatwell Guide [72]. The Eatwell Guide is the UK Government's dietary advice presented as an infographic. The five groups are:

- fruit and vegetables
- potatoes, bread, rice, pasta or other starchy carbohydrates
- dairy or dairy alternatives
- beans, pulses, fish, eggs, meat and other protein.
- foods high in fat and/or sugar

I created two additional categories to capture foods that were not represented in the Eatwell Guide. "Miscellaneous foods" contains foods that did not fit into one of the above categories, for example tea, coffee, mineral water, and seasonings. "Composite foods" contained foods that could fit in more than one category such as pizzas and pasta-based ready-meals.

The percentage of fruit, vegetables, meat, fish, dairy, cereals and wholegrain was also recorded. Manufacturers are not required to state the amount of an ingredient present unless a reference is made in the product name (quantitative ingredients declaration, [118]), therefore it was anticipated that this information would be largely incomplete so where possible, estimates were made to the nearest 10% - details regarding missing nutritional data is reported in Chapter 5.

In order to assess the nutritional composition of products carrying health-related claims (Chapter 5) the nutritional information was recorded from the packaging for each product. Data for the following nutrients were extracted per 100 grams, energy, protein, carbohydrates, total sugars, total fat, saturated fat, fibre, and sodium. The recommended serving size was also recorded. These nutrients were chosen as Council Directive 90/496/EEC [26] states that where nutrition labelling is present on foods it must contain either 'group 1' nutrients – the energy value and the amounts of protein, carbohydrate and fat, or 'group 2' nutrients - energy value and the amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium.

In December 2016 Regulation (EC) 1169/2011 [22] governing nutritional declarations and other aspects of food labelling came into effect. Under this regulation manufacturers must provide the following information; energy (kJ and kcal), and in grams, protein, carbohydrates, total sugars, total fat, saturated fat, and salt. Fibre is considered as a 'supplementary' nutrient, along with mono-unsaturates, poly-unsaturates, polyols, starch, and vitamins and minerals, and supplied on a voluntary basis. However, if a health or nutrition claim is made in relation to a supplementary nutrient then it is mandatory to declare the amount present.

At the time of data collection nutrition declarations were not yet mandatory so it was anticipated that the nutritional information would not always be provided. Therefore, an additional data source was used to supplement missing data. The UK Nutrient Databank [119] is a dataset of approximately 8000 foods used for analysis of nutritional research studies in the UK. For each product in the dataset, a similar product was found in the UK Nutrient Databank (for example, Appletiser would be matched to 'carbonated apple juice beverage'). Where only partial nutritional information was available the similar food from the UK Nutrient Databank was merged with the manufacturer nutritional information. The nutritional information from the manufacturer always took precedence over the supplemented data from the UK Nutrient Databank. This also enabled foods without the full nutritional information on the packaging to be analysed by a range of nutrient profile models. Internal validity assessments were conducted to assess the strength of the correlation of the nutritional information from the UK Nutrient Databank and that on the packaging. The correlation of each nutrient was examined in turn and any outliers were inspected. Where this revealed outliers (i.e. when the nutritional information on the packaging was vastly different from the substitute product) a new substitute product was sought (discussed further in Chapter 5).

The health and nutrition claims were recorded in a separate sheet. This was partly to allow data extraction and claim extraction to occur in separate stages, but to also prevent having to

enter repeated lines of product data for additional claims. In the 'Claim information' sheet, each claim was recorded as a new line of data; if a product did not carry any claims then 'no claim' was recorded. Using the product ID code, each line of claim data was matched to the corresponding product.

During the data extraction phase data extractors were encouraged to feedback to the collaborators with any queries, answers were then shared with the entire team so that all data extractors were privy to the same information. However, it was expected that discrepancies would still occur, so a reliability assessment was conducted. The first ten products in each country were extracted and then the partially complete database and pictures were sent to a central researcher. This person then checked that all the relevant information had been extracted correctly, and amendments were discussed and again shared with the entire team.

Once all the data had been collected, and extracted into the spreadsheet, the completed databases were returned for data cleaning. Where possible data cleaning was conducted in STATA so that any changes could be recorded and were easily reversible.

Health-related claim definitions

Various categorisations for health and nutrition claims exist. This study uses the health-related claim definitions and taxonomy developed by the INFORMAS project [24] which in turn, were based on Codex Alimentarius guidelines [70]. The EU Regulation (EC) 1924/2006 [38] also draws considerably upon these Codex guidelines for its categorisation of health-related claims. A comparison of the way the INFORMAS project, the EU Regulation, and the CLYMBOL project, categorises claims is presented in Table 3.2.

The full INFORMAS nutrition information taxonomy is presented in Figure 1.2 (page 8), this thesis is concerned with the section of the taxonomy presented in Figure 3.1 [23].

Figure 3.1 INFORMAS Taxonomy – Health-related claims [23]

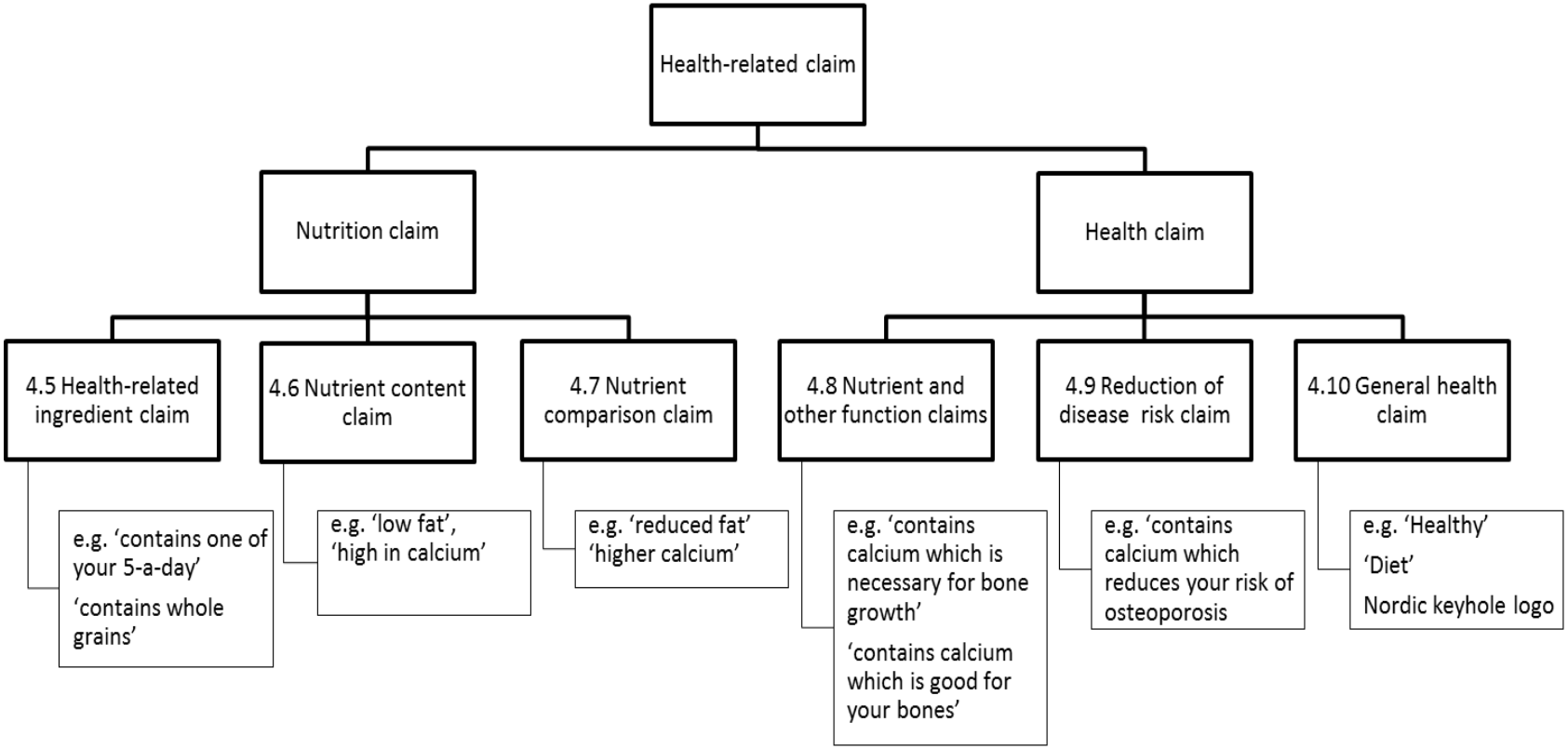


Table 3.2: Definitions of nutrition claims and health claims (and sub-types) using the INFORMAS taxonomy and EU categories

INFORMAS categories	***IINFORMAS (Codex) definition [70]***	***EU categories (Regulation 1924/2006 (Amended and corrected) by 04.03.2008 [38]***	***EU definition***	**Notes**
Nutrition claim by:	*Nutrition claim* – 'any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.' (CAC/GL 23-1997)	*Nutrition claims*	*Nutrition claim* –' any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: (a) the energy (calorific value) it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or (b) the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain;	Codex and EU define 'nutrient'. EU defines 'other substance'
a) Health-related ingredient claims	*Health-related ingredient claim* – any representation which states, suggests or implies that a food has particular nutritional properties not related to its energy value or to the content of protein, fat and	EU Regulation has no specific name for this type of nutrition claim CLYMBOL calls these claims *health-related ingredient*		Under the EU Regulation nutrition claims can be for substances other than nutrients that have nutritional or physiological effects) (Article 2)

INFORMAS categories	***IINFORMAS (Codex) definition [70]***	***EU categories (Regulation 1924/2006 (Amended and corrected) by 04.03.2008 [38]***	***EU definition***	**Notes**
	carbohydrates, vitamins and minerals but related to the content of an ingredient'	*claims*		EU Regulation gives conditions for this type of claims in Article 8 and 9
b) Nutrient content claims	*Nutrient content claim* – 'a nutrition claim that describes the level of a nutrient contained in a food [or its energy value]' (CAC/GL 23-1997). [In this taxonomy nutrient content claims include 'Non-addition claims' defined by CAC/GL 23-1997 as ' any claim that a ingredient [nutrient] has not been added to a food, either directly or indirectly. The ingredient [nutrient] is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food']	EU Regulation has no specific name for this type of nutrition claim CLYMBOL calls these claims *nutrient content claim*		EU Regulation gives conditions for this type of claims in Article 8
c) Nutrient comparison claims	*Nutrient comparative claim* – 'a [nutrition] claim that compares the nutrient levels and/or energy value of two or more foods.' (CAC/GL 23-1997)	EU Regulation calls these claims *comparative [nutrition] claims* CLYMBOL calls these claims *nutrient comparison claims*		EU Regulation gives conditions for this type of claim in Article 9

INFORMAS categories	***IINFORMAS (Codex) definition [70]***	***EU categories (Regulation 1924/2006 (Amended and corrected) by 04.03.2008 [38]***	***EU definition***	**Notes**
Health claims by:	*Health claim* – 'any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.' (CAC/GL 23-1997)	*Health claims*	Health claim – 'any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;	
a) Nutrient and other function claims	*Nutrient function claim* – 'a [health] nutrition claim that describes the physiological role of the nutrient in growth, development and functions of the body.' (CAC/GL 23-1997) [Although Codex classifies nutrient function claims as nutrition claims it seems more logical to classify them as health claims] *Other function claim* – health *'*claims concerning specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.' (CAC/GL 23-1997)	*Health claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body* CLYMBOL calls these claims *nutrient and other function claims*		EU Regulation gives conditions for this type of claim in Article 13 .1(a)

INFORMAS categories	***IINFORMAS (Codex) definition [70]***	***EU categories (Regulation 1924/2006 (Amended and corrected) by 04.03.2008 [38]***	***EU definition***	**Notes**
No specific category in INFORMAS. Claims classified as nutrient and other function claims		*Health claims describing or referring to psychological and behavioural functions*		EU Regulation gives conditions for this type of claim in Article 13 .1(b)
No specific category in INFORMAS. Claims classified as general health claims		*Health claims describing or referring to slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet*		EU Regulation gives conditions for this type of claim in Article 13 .1(c)
c) General health claims	*General health claim* – a health claim concerning the general beneficial effects of the consumption of foods or their constituents on health.	No specific name for this type of health claim (but health claims can make 'reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well being '		EU Regulation acknowledges the existence of this type of claim in Article 10.3
b) Reduction of disease risk claims	*Reduction of disease risk claim* – health 'claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.' (CAC/GL 23-1997)	*Reduction of disease risk claims*	*Reduction of disease risk claim* – 'any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;	EU Regulation gives conditions for this type of claim in Article 14
No specific category in		*Health claims referring to*		EU Regulation gives conditions

INFORMAS categories	***IINFORMAS (Codex) definition [70]***	***EU categories (Regulation 1924/2006 (Amended and corrected) by 04.03.2008 [38]***	***EU definition***	**Notes**
INFORMAS. Claims classified either as nutrient and other function claims, general health claims or reduction of disease risk claims		*children's development and health*		for this type of claim in Article 14

Nutrition claims

A 'nutrition claim' refers to any claim which *"states, suggests or implies that a food has a particular beneficial nutritional properties due to…the energy (calorific value)..or the nutrients or other substances…" (page 9, [38]).*

Nutrition claims can be divided into the following claim types:

- Nutrient content claims: a nutrition claim that describes the level of a nutrient within a food (e.g. 'low in fat', 'source of calcium', 'high in vitamin C')
- Nutrient comparative claims: a nutrition claim that compares the value of at least two foods (e.g. '50% reduction in salt', 'increased fibre')
- A new category was created called 'health-related ingredient claims'. This category refers to nutrition claims relating to a substance or ingredient rather than a nutrient, for example "high in fruit". This was included as a separate category as there are guidelines for mentioning nutrients in claims; e.g. in order to use the nutrition claim 'low calorie' the food must contain less than 40kcal per 100g. Similar thresholds exist for fat, saturated fat, protein, sugars, fibre, sodium, cholesterol, and vitamins and minerals.

Health claims

"A 'health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health" ([38], page 9).

Health claims are divided into the following four groups:

- 'General health claims' refer to general statements relating to the healthiness of a product 'e.g. 'healthy', 'goodness' etc.) but do not reference a nutrient or specific body function.

- ‘Nutrient and other function claims’ refer to the role of a nutrient or substance relating to growth, development, and functions of the body.
- ‘Reduction of disease risk claims’ refer to claims that a food or food category reduce the risk of the development of a human disease. Finally, health claims may also refer to children’s development.
- ‘Children's development and health claims’ refer to claims that suggest, imply or state that the consumption of the food (or its constituents) is beneficial for children’s development and health.

Statistical analyses

Further details about the statistical analyses (including justifications) are included in the corresponding chapters. All statistical analyses were conducted in STATA [75].

To assess the prevalence of claims the proportion of foods carrying health claims was reported for the whole database and then stratified by country and by food group. Confidence intervals and standard errors were calculated in STATA assuming a binominal distribution of the proportion of foods in the population.

Nutritional quality of foods carrying claims (Chapter 5)

The nutritional information extracted from the food labels was examined to assess the nutritional quality of foods carrying health-related claims. The mean levels, per 100g, of energy, protein, carbohydrates, total sugars, total fat, saturated fat, fibre, and sodium were calculated for the foods carrying one or more health claims (including health symbols); nutrition claims; health-related claims (i.e. one or more health or nutrition claims), and for foods carrying no health-related claims. Nutrient levels per 100g were chosen as the base for

comparison as portion size data were often not provided by the manufacturers. As the data were not normally distributed (with large spikes at zero for most nutrients) a non-parametric Mann-Whitney two sample test was conducted to determine if differences were statistically significant at the p = 0.05 level.

A nutrient profile model currently used for the regulation of health-related claims in Australia and New Zealand, the FSANZ NPSC [47] was applied to the database using STATA do-files. The FSANZ NPSC was chosen for this analysis as it scores foods based on multiple nutrients/components, including: energy content, and total sugars, saturated fat, sodium, protein, and fibre (in grams per 100g/ml), six of the eight nutrients assessed in Chapter 5. The do-files were checked for errors by another researcher. The aim of this analysis was to assess the impact of using a nutrient profile model on health-related claim prevalence. I conducted a scenario analysis where products that carried at least one health-related claim but failed the FSANZ NPSC criteria were deemed as not carrying a health-related claim. I then estimated the mean levels of nutrients for foods carrying health-related claims and foods not carrying health-related claims and the new prevalence of health-related claims under this scenario.

Comparisons between nutrient profile models used for the regulation of health-related claims (Chapter 6)

In this chapter, three nutrient profile models were applied using STATA do-files. The strictness of the models was measured by examining the proportion of foods each model allows to 'pass' (along with the 95% confidence intervals). The agreement between the nutrient profile models was assessed through the percentage agreement and Cohen's kappa score with the standard error.

As in Chapter 5, I conducted scenario analyses where each of the nutrient profile models in turn were used to regulate health-related claims. Again, the scenario health-related claim

prevalence and the scenario mean levels of nutrients were estimated using each nutrient profile model.

Modelling the effect of health-related claims on health outcomes in the UK (Chapter 7)

In this chapter I built a front-end model for an established disease scenario model: the Preventable Risk Integrated ModEl (PRIME) [62]. This model uses data from meta-analyses of randomised controlled trials and prospective cohort studies to link modifiable risk factors (e.g. diet and physical activity) to non-communicable disease mortality.

Using data presented in previous chapters to parameterise the model (e.g. prevalence of health-related claims, effect size of claims on purchasing behaviour), I first modelled the effects of different health-related claim scenarios on the diet and then, using PRIME, modelled the health outcomes associated with these changes.

Three groups of scenarios are modelled in Chapter 7. The first model refers to the removal of health-related claims ('Health-related claims removed'). This was to assess the effect of health claims on health outcomes. Here, the counterfactual scenario that was modelled was that all health claims were removed from food packaging, and the difference between the baseline (with claims) and the counterfactual is therefore assumed to be the health effect of health-related claims.

Models 2-4 refer to the restriction of health-related claims through the use of a nutrient profile model. ('Health-related claims restricted'). Models 5-7 reflect a situation where health-related claims are regulated with a nutrient profile model but, unlike the 'Health-related claims restricted' scenarios, it is assumed that manufacturers will reformulate products so that the claim prevalence is maintained at current levels ('Health-related claims reformulated').

Data sources

In order to configure PRIME to address these scenarios the following health-related claim information is required:

- The impact of health-related claims on dietary choices (Chapter 2),
- The prevalence of health-related claims (Chapter 4),
- The difference in nutritional composition of foods that carry health-related claims and those that do not (Chapter 5),
- The expected difference in nutritional composition of foods if health-related claims were only permitted on foods that pass a nutrient profile model (Chapter 6).

The following population-level estimates are required:

- UK population nutrient intake data
- UK population and mortality data

UK population nutrient intake data

These data were taken from the Living Costs and Food (LCF) survey [120] and the National Diet and Nutrition Survey (NDNS, [10]).

The LCF survey is an annual survey of household expenditure conducted in the UK [120]. In this survey more than 11000 households in Great Britain and, separately, 300 households in Northern Ireland are invited to participate. In the 2013 survey approximately half (48%) of households agreed to participate and provided enough information for their responses to be included in the analyses.

The LCF survey is intended to be representative of purchases by the UK population. A clustered randomised sampling frame is used to identify households through using a database of all known addresses and postcodes in the UK (Postcode Address File, PAF, [121]). The LCF survey invites private households (i.e. not hostels, hotels, boarding schools, public institutions, etc.) to participate. A 'household' refers to a person living alone or to a group of people living at the same address. Household members do not need to be related, nor be British subjects, to be eligible to participate, but they do need to share cooking facilitates and a communal area (e.g. a living room or dining area). Approximately 6000 households participate in the study, all members of the household (including children) are encouraged to participate.

Over a period of two weeks, members of participating households are instructed to keep a detailed record of daily expenditure. The average purchases per person, per week are then calculated. The LCF measures the sales (in grams or ml) by food group, from this the nutrient intake is calculated by converting the grams of each food group purchased into nutrients from each gram purchased. The average nutrient intake is calculated using nutrient composition data from the UK Nutrient Databank [119] . In this databank the inedible parts of foods (e.g. banana peels, egg shells etc.) are not included within the estimates for the nutrient composition, however it is assumed that all of the edible part of the food is consumed.

The LCF data are weighted to make the data representative of the population demographics (region, age group and sex) and also to reduce the effect of non-response bias. The weighted average intake is determined by combining the nutrient composition data with the purchase data. The LCF categorises foods into approximately 500 food (and sub-food groups). To make the LCF data compatible with the health-related claim estimates I re-categorised the food groups used by the LCF survey [122] into the UK Eatwell Guide categories.

To model changes in the distribution of dietary variables, the standard deviations (SD) of the mean nutrient intakes are required. This allows us to examine how the intake of nutrients is

dispersed across the population - a small SD indicates that a greater proportion of the population has an intake of a nutrient close to the mean, whereas a larger SD indicates that there is more variation in intake. As these data are not provided in the LCF survey the SDs from the National Diet and Nutrition Survey (NDNS) were used instead. The SDs for the overall intake of fruit, vegetables, fibre, total fat, saturated fat, salt, mono-unsaturated fat, poly-unsaturated fat, and cholesterol were taken from the NDNS, which uses the same nutrient variables as the LCF. The same SDs were used for the baseline and the counterfactual scenarios therefore the model assumes that the distribution of the intake of nutrients does not change.

The NDNS is a survey of food consumption in the UK. It collects detailed information on food consumption, nutrient intake, and nutritional status, which are collected from a representative sample of approximately 1000 people per year. Years 1-4 of the survey contains data for approximately 7000 people (3450 adults aged 19 years and over and 3378 children aged 1.5 to 18 years). Unlike the LCF only one adult and/or one child from each household are invited to participate. Over a period of four consecutive days, participants are instructed to keep a food diary. In addition to this a blood sample is taken to assess biochemical markers of nutrient intakes and a urine sample is collected to measure the salt intake. The start day is randomly selected so that each weekday is equally represented in the final database. In years 1-4 there was a 56% response rate and, in total, there was at least 3 days' worth of data for 6828 participants [10].

The NDNS measures consumption of both unpackaged and pre-packaged foods. Whilst the NDNS data offers greater detail of food consumption then the LCF survey, the LCF is a more appropriate data source for this chapter's analyses as it measures food purchases and the analyses presented in this thesis relate to pre-packaged foods available to purchase rather than food consumption. For example, the health-related claim prevalence estimates (Chapter

4), were from a cross-sectional survey of pre-packaged foods. The evaluation of the nutritional quality of foods carrying health-related claims (Chapter 5) was also performed on this data - the analyses are not weighted by sales data nor do they take food wastage into account. This may mean that the data overestimates consumption as recent estimates of food wastage suggest that purchased food with a retail value of approximately £13 billion was thrown away rather than consumed [123].

UK population estimates

The estimates for the population age and sex data were taken from the Annual Mid-year Population Estimates [124] produced by the Office for National Statistics. The mid-year estimates (MYE) are based upon the census (projected for non-census years by trends in births and deaths) and refer to the estimated populations on the 30th June each year for England, Wales, Scotland, and Northern Ireland. The MYE consider trends in migration statistics as well as birth and death certificate registrations.

UK mortality data

The mortality data were collated from data for the registered deaths for England and Wales [125], Scotland [126], and Northern Ireland [127]. These data are used to observe social and demographic trends within the UK. After a death, once a medical certificate has been issued by a doctor, the death must be registered with the Register office within 5 days (within 8 days in Scotland). When the death is registered the details such as the deceased individual's age, sex, and (usually) the cause of death are recorded. Occasionally there are delays in registering the death (e.g. if awaiting for a coroner's verdict for the cause of death) therefore the mortality data used in this chapter refers to the number of registered deaths rather than the numbers of actual deaths.

Summary

This chapter provided a summary of the methods used in Chapters 4-7 of this thesis. Chapters 4 and 5 estimate the prevalence of health-related claims and the nutritional compositions of foods carrying claims. Both chapters use data from a cross-sectional survey of pre-packaged foods collected as part of the pan-European CLYMBOL project. This dataset is a unique data source as there has not previously been a survey of health-related claims on food packaging in which foods were randomly sampled across all food categories, across multiple countries. Whilst there are some limitations to the dataset (discussed in the next chapter) it remains a good resource for future studies. Chapter 6 examines the strictness and agreement between three nutrient profile models used, or proposed for use, for the regulation of health-related claims, and the potential impact of on the prevalence of health-related claims. Finally, Chapter 7 combines the data presented in the preceding chapters with population-level estimates for nutrient intake and mortality rates, and a disease risk model to estimate the impact of health-related claims on UK mortality rates.

4. The prevalence of health-related claims

Introduction

In the previous chapter I discussed the methods used to develop a representative sample of pre-packaged food available to purchase in Germany, the Netherlands, Spain, Slovenia, and the United Kingdom. In this chapter I present the results of this survey and discuss other studies that have also measured health-related claim prevalence (the proportion of foods that carry a health-related claim).

Background

In Chapter 2 I presented the results of a systematic review on the effect of health-related claims on dietary choices. The results of the meta-analyses suggest that health-related claims may increase the likelihood of being purchased and/or consumed by up to 75% (OR 1.75, 95% CI 1.60, 1.91). However, these results are largely based on small laboratory studies. In order to measure the impact of health-related claims on a population level, we must first estimate how many foods carry health-related claims.

Much of the previous research on the prevalence of health-related claims has been conducted outside of Europe. For example, a survey of Australian foods found that 14% of products carried a health claim and 51% of products carried a nutrition claim [128, 129]. Similar findings were observed in a Canadian survey where 48% of foods carried a health or nutrition claim [130], and in the USA where 49% of foods carried a health-related claim [131]. Cross-country comparisons of health-related claim prevalence are rare, however, one international study compared the prevalence of nutrition claims on two food types (crisps and biscuits) in 16 countries and found large differences in the prevalence of health-related claims ranging from 4% in the UAE to 71% in Argentina [132].

Within Europe, the rules around the use of health-related claims on foods labels were set out in Regulation (EC) 1924/2006 on nutrition and health claims made on foods [38]. Prior to this regulation the rules regarding the use of health-related claims varied between EU member states which may have restricted trade between countries. The FLABEL (Food Labelling to Advance Better Education for Life) project confirmed these differences through conducting surveys of nutrition labelling in the 27 EU Member States and Turkey. The survey found a very low prevalence of health claims and large country differences in the prevalence of nutrition claims [28]. However, this survey only sampled products from five food categories therefore may not be an accurate representation of the overall health-related claim prevalence across all food categories. Furthermore, the survey was conducted prior to when many of the aspects of Regulation (EC) 1924/2006 were compulsory, and only measured whether a claim was present or not – so we cannot determine what types of health-related claims are most common nor whether their nutritional compositions are better.

Within the UK, the Foods Standards Agency (FSA) conducted a more detailed survey of health-related claims but this was an audit of the types of health claims and did not include any foods that did not carry any health-claims, therefore it cannot be used to estimate the overall health-related claim prevalence [112].

Within Europe, there have been a number of single-country studies that do measure the prevalence of health-related claims but few of these studies use a sample of foods that are representative of pre-packaged foods that are available to purchase in-store. Previous research has commonly focussed on foods that are commonly eaten [111, 133, 134], and/or studied foods in one food category (e.g. dairy foods [135]), or due to differing sampling methods (e.g. using a retailer's website as a sampling frame [136]) may not be an accurate representation of the prevalence of health-related claims of foods available to purchase in-stores nor of foods available to purchase across different store types.

To the best of my knowledge, there has not been a European multi-country survey of health-related claim prevalence. Therefore, the research questions for this chapter are:

1. What is the prevalence of health-related claims in the UK, Germany, the Netherlands, Spain, and Slovenia?
    a. How does the prevalence differ by food group and/or country?
2. What is the prevalence of the sub-types of health-related claims?
    a. Which nutrients and/or food groups do they refer to?

Methods

The following information was discussed in the previous chapter: definitions, sampling frame and methods, pilot studies, and data extraction. A summary is provided below.

Using a stratified random sampling method, approximately 2000 pre-packaged foods available to purchase in store were randomly selected and purchased in the UK, Germany, the Netherlands, Spain and Slovenia. In each country 400 foods were sampled; 250 from a large supermarket or a national retailer, 75 foods from a neighbourhood store, and 75 foods from a discounter store (exact numbers given in Table 3.1). The sample size was decided through power calculations to answer the research question 'what is the prevalence of health-related claims' and to detect a 10% difference in prevalence rates between countries. Once the foods were purchased the food labels were retained for data extraction. Photographs were taken of all products that contained a health-related claim. The product information, nutritional composition, and health-related claim information was recorded. Foods were initially categorised into the food grouping used by Dunford et al [117] and then later re-categorised into the UK Eatwell Guide categories [72].

Data extraction

For each product the following information was recorded in Excel:

1. Product information
    - The country and type of store the product was sampled from.
    - The price of the product.
2. The presence of the following information on food labels was recorded as a binary variable:
    - Nutrition labelling
        - Nutrient declarations: e.g. tables and/or lists of the products' nutritional composition) were present on the food label.
        - Supplementary nutrition information
            - Nutrient specific systems (e.g. Guideline Daily Amounts [GDAs], Traffic Light Labelling)
            - Summary indicator systems (with details recorded if they were present)
    - Other information
        - List of ingredients
        - Presence of statements relating to: dairy/lactose, wheat/gluten, vegetarian claims, and artificial preservatives, colours and flavours.
3. The following information, where it was provided, was recorded from the food label:
    - Recommended serving size
    - Energy (Kj and Kcal per 100g)
    - Protein, carbohydrate total sugars, total fat, saturated fat, and fibre (g per 100g)
    - Sodium (mg per 100g), if the salt content was provided it was converted to sodium values by dividing the amount of salt by 2.5.

4. Information required for the selected nutrient-profile models

Nutrient profiling is the “science classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health.” [44]. Nutrient profile models are the algorithms used to make these classifications and/or rankings. The nutrient profile models chosen for this study were all category-specific models, they have different nutritional criteria for different food groups, therefore the foods in the database had to be categorised into each of the food groups used by each model. Further details will be provided in Chapter 5.

In order to apply the nutrient profile models the following compositional information was recorded from the food label:

- % fruit and vegetables
- % meat
- % fish
- % dairy constituents
- % of cereals
- % bread/rice/pasta
- % wholegrain
- % soy protein

Where this information was not present on the food label estimates were made based on a similar product and/or the matched product in the UK Nutrient Databank. Further details will be provided in Chapter 5.

Health-related claim information

The health-related claim was recorded verbatim as it appeared on the food label, first in the local language and then translated into English if required. For pictorial and/or symbolic claims a description was given. The following information was also recorded:

- The number of times the same claim appears on the packaging
- The position of the claim (FOP, FOP plus elsewhere, Not-FOP)
- Whether the claim was worded or pictorial or whether the claim was a health logo
- What was the target population of the claim (e.g. adults, children, pregnant women etc.)? If the target was not specified in the claim then the claim was deemed as a non-targeted claim and the claim target was recorded as "none".
- Which nutrient(s) or other substance(s) was referred to in the claim
- Whether the claim was a:
    - Nutrition claim, if so whether it was a:
        - Health-related ingredient claim
        - Nutrient content claim
        - Nutrient comparison claim
    - Health claim, if so whether it was a:
        - General health claim
        - Nutrient and other function claim
        - Reduction of disease risk claim
        - Children's development and health claim
- Whether the claim was specific or non-specific. A non-specific claim is a claim that does not refer to a specific health effect or function (e.g. "healthy", "good for you"). If the claim was specific the claim then the following information was also captured and coded:

- The effect direction. This refers to the direction of the effect on the function referenced in the claim. Functions can be improved (e.g. “helps improve oral health”) or they can be maintained (“e.g. “helps maintain oral health”). For some claims, the effect direction can be reduced (e.g. “May reduce restlessness”).
- The effect certainty. This refers to the certainty of the relationship between the nutrient or ingredient and the health effect, for example some claims use qualifiers such as ‘may’, ‘helps’, or ‘contributes’.
- Framing. Health related claims may be framed positively i.e. as a gain (e.g. “calcium helps improve oral health”) or negatively i.e. as a reduction (e.g. “…reduces blood cholesterol”).
- Disease and health state. The disease and/or health state referenced in the claim were categorised using a well-established framework: the International Classification of Functioning, Disability and Health (ICF) [16]. The ICF was developed by the World Health Organization and is used internationally to measure health and disability. The ICF contains a classification system for body functions and body structures. The body functions are broken down into eight different chapters;

    1. Mental functions
    2. Sensory functions and pain
    3. Voice and speech functions
    4. Functions of the cardiovascular, haematological, immunological and respiratory systems
    5. Functions of the digestive, metabolic and endocrine systems
    6. Genitourinary and reproductive functions
    7. Neuromusculoskeletal and movement-related functions

8. Functions of the skin and related structures.

Results

The data recorded from the food labels was entered into Excel and analysed using Stata V11 [75].

Missing data

Missing nutritional data is discussed in Chapter 5, missing information required to apply the nutrient profile models is discussed in Chapter 6.

Descriptive statistics

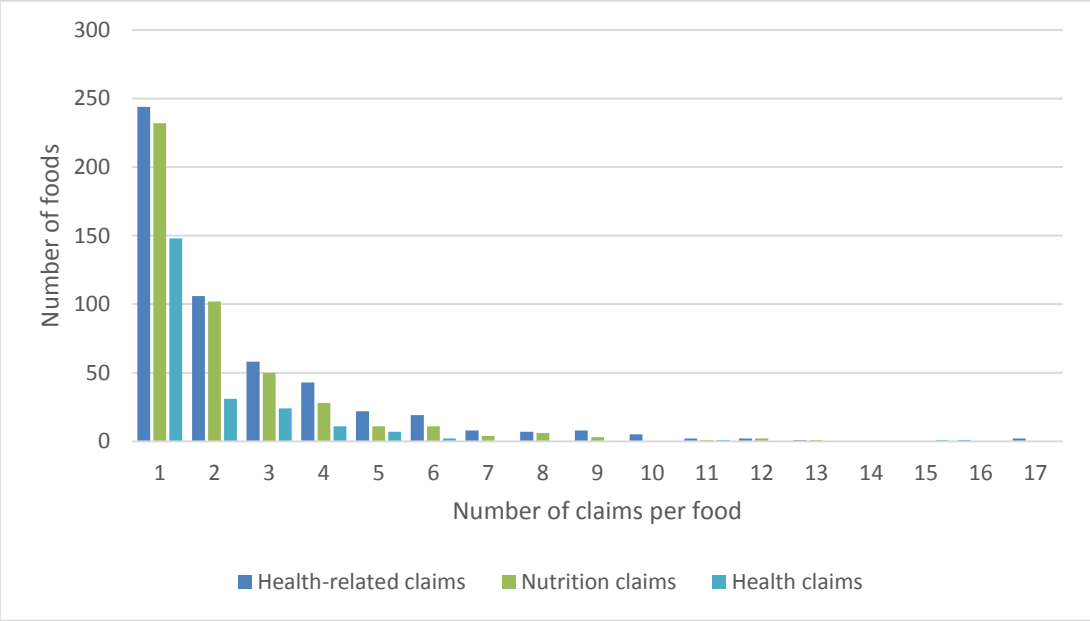
Of the 2034 foods sampled, 528 foods carried at least one health-related claim and a total of 1369 health-related claims were found (Table 4.1). Of foods that carry health-related claims, the mean number of claims per product was higher for nutrition claims (mean 2.2, SD 1.8) than for health claims (mean 1.8, SD 1.6).

Of the products carrying at least one health-related clams (n=528), 3% (n=13) carried more than 10 claims, 6 of these products were Foods high in fat and/or sugar such as high sugar cereals and high sugar drinks, 4 of the foods were baby foods. The highest number of health-related claims found on a single food was 17, two baby foods had this many claims, one each from Spain (product ID 31) and Germany (product ID 357). Germany had the product with the highest number of nutrition claims (n=13), the food was a chocolate product (product ID 21). Germany also had the product with the highest number of health claims; 15 health claims were found on a baby food (product ID 357).

Table 4.1 The number of health-related products per product

Type of claim	Total number of claims found	Number of foods with at least 1 claim	Mean number of claims per product (SD) of foods with at least 1 claim	Highest number of claims on a food
Health-related claims	1369	528	2.6 (2.4)	17
Nutrition claims	970	451	2.2 (1.8)	13
Health claims	399	225	1.8 (1.6)	15

Fig 4.1 The number of health-related claims per product



Types of foods sampled

In total, 2034 foods were sampled, ranging from 398 in the UK to 416 in Slovenia. Foods high in fat and/or sugar made up the largest proportion of the database (36%, 95% CI 34%, 38%). The types of foods in this category included; chocolates and sweets (20%), biscuits (10%), soft

drinks (9%), and cakes, muffins and pastries (7%). Dairy or dairy alternatives and Fruit and vegetables were the smallest categories (both 8%, 95% CIs 7%, 9%) (Table 4.2).

There was little country variation in the proportions sampled of the following food groups; Dairy or dairy alternatives, Fruit and vegetables, and Potatoes, bread, rice, pasta or other starchy carbohydrates. The greatest country-level difference was observed for Foods high in fat and/or sugar, which ranged from 32% of the products sampled from Spain, to 42% of the Slovenian products. Miscellaneous foods ranged from 10% in the UK to 17% in Germany, and Beans, pulses, fish, eggs, meat and other protein ranged from 12% in Slovenia and the UK, to 19% in Spain. A Pearson's chi-squared (X^2) test was conducted to test whether the differences in proportion of Eatwell Guide food groups sampled in each country were statistically significant. There were significant differences observed for the proportion of Composite foods (X^2 = 36.3, 4 degrees of freedom [df], $p<0.0001$). There was also significant country differences in the proportion of Potatoes, bread, rice, pasta or other starchy carbohydrates (X^2 = 11.0, 4df, $p<0.05$) and for Beans, pulses, fish, eggs, meat, and other protein (X^2 = 11.1, 4df, $p<0.05$).

Table 4.2 Types of foods sampled (n, %, 95% CI)

Country	Potatoes, bread, rice, pasta or other starchy carbohydrates	Dairy or dairy alternatives	Foods high in fat and/or sugar	Beans, pulses, fish, eggs, meat and other protein	Fruit and vegetables	Composite foods	Miscellaneous	Total
Germany	31, 8% (5%, 10%)	26, 7% (4%, 9%)	144, 36% (31%, 41%)	56, 14% (11%, 17%)	35, 9% (6%, 12%)	38, 10% (7%, 12%)	69, 17% (14%, 21%)	399, 20% (18%, 21%)
Netherlands	39, 9% (7%, 12%)	36, 9% (6%, 11%)	156, 38% (33%, 42%)	66, 16% (12%, 19%)	30, 7% (5%, 10%)	36, 9% (6%, 11%)	53, 13% (10%, 16%)	416, 20% (19%, 22%)
Spain	30, 7% (5%, 10%)	40, 10% (7%, 13%)	130, 32% (28%, 37%)	78, 19% (15%, 23%)	32, 8% (5%, 11%)	38, 9% (7%, 12%)	57, 14% (11%, 17%)	405, 20% (18%, 22%)
Slovenia	56, 13% (10%, 17%)	30, 7% (5%, 10%)	173, 42% (37%, 46%)	51, 12% (9%, 15%)	26, 6% (4%, 9%)	20, 5% (3%, 7%)	60, 14% (11%, 18%)	416, 20% (19%, 22%)
UK	38, 10% (7%, 12%)	30, 8% (5%, 10%)	137, 34% (30%, 39%)	49, 12% (9%, 16%)	36, 9% (6%, 12%)	68, 17% (13%, 21%)	40, 10% (7%, 13%)	398, 20% (18%, 21%)
Total	**194, 10% (8%, 11%)**	**162, 8% (7%, 9%)**	**740, 36% (34%, 38%)**	**300, 15% (13%, 16%)**	**159, 8% (7%, 9%)**	**200, 10% (9%, 11%)**	**279, 14% (12%, 15%)**	**2034, 100%**
P value	**0.026**	**0.426**	**0.062**	**0.026**	**0.563**	**0.000**	**0.052**	**-**

Table 4.3. Health-related claim prevalence by claim type, country, and food group (n, %, 95% CI)

	Potatoes, bread, rice, pasta or other starchy carbohydrates	Dairy or dairy alternatives	Foods high in fat and/or sugar	Beans, pulses, fish, eggs, meat and other protein	Fruit and vegetables	Composite foods	Miscellaneous	Total
Foods carrying one or more…								
Health claims								
Germany	2, 7% (-2%, 15%)	5, 19% (4%, 35%)	11, 8% (3%, 12%)	6, 11% (3%, 19%)	3, 9% (-1%, 18%)	0, 0%	10, 15% (6%, 23%)	37, 9% (6%, 12%)
Netherlands	2, 5% (-2%, 12%)	9, 25% (11%, 39%)	21, 14% (8%, 19%)	7, 11% (3%, 18%)	7, 23% (8%, 39%)	3, 8% (-1%, 18%)	11, 21% (10%, 32%)	60, 14% (11%, 18%)
Spain	2, 7% (-2%, 16%)	6, 15% (4%-27%)	5, 4% (5%, 7%)	1, 1% (-1%, 4%)	1, 3% (3%, 9%)	0, 0%	14, 25% (13%, 36%)	29, 7% (5%, 10%)
Slovenia	11, 20% (9%, 28%)	8, 27% (11%, 43%)	15, 9% (5%, 13%)	2, 4% (-1%, 9%)	1, 4% (-4%, 11%)	2, 10% (4%, 24%)	13, 22% (11%, 32%)	52, 13% (9%, 16%)
UK	6, 16% (4%, 27%)	6, 20% (5%, 35%)	14, 10% (5%, 15%)	8, 16% (6%, 27%)	4, 11% (7%, 22%)	1, 2% (-1%, 4%)	5, 13% (2%, 23%)	44, 11% (8%, 14%)
Total	**23, 12% (7%, 16%)**	**34, 21% (15%, 27%)**	**66, 9% (7%, 11%)**	**24, 8% (5%, 11%)**	**16, 10% (5%, 15%)**	**6, 3% (1%, 5%)**	**53, 19% (14%, 24%)**	**222, 11% (10%, 12%)**
P value	**0.129**	**0.761**	**0.081**	**0.047**	**0.067**	**0.044**	**0.472**	**0.016**
Nutrition claims								
Germany	7, 23%	7, 27%	20, 14%	11, 20%	8, 23%	3, 8%	14, 20%	70, 18%

	Potatoes, bread, rice, pasta or other starchy carbohydrates	Dairy or dairy alternatives	Foods high in fat and/or sugar	Beans, pulses, fish, eggs, meat and other protein	Fruit and vegetables	Composite foods	Miscellaneous	Total
	(8%, 38%)	(10%, 44%)	(8%, 20%)	(9-30%)	(9%, 37%)	(-1%, 17%)	(11%, 30%)	(14%, 21%)
Netherlands	5, 13% (2%, 24%)	11, 31% (15%, 46%)	29, 19% (12%, 25%)	8, 12% (4%, 20%)	7, 23% (8%, 39%)	0, 0%	13, 25% (13%, 36%)	73, 18% (14%, 21%)
Spain	7, 23% (8%, 39%)	22, 55% (39%, 71%)	20, 23% (16%, 30%)	9, 12% (4%, 19%)	3, 9% (-1%, 20%)	8, 21% (8%, 34%)	14, 25% (13%, 36%)	93, 23% (19%, 27%)
Slovenia	19, 34% (21%, 47%)	9, 30% (13%, 47%)	31, 18% (12%, 24%)	2, 4% (2%, 9%)	4, 15% (1%, 30%)	2, 10% (-4%, 24%)	11, 18% (8%, 28%)	78, 19% (15%, 23%)
UK	15, 40% (24%, 55%)	15, 50% (32%, 68%)	42, 31% (23%, 38%)	16, 33% (19%, 46%)	24, 67% (51%, 82%)	15, 22% (12%, 32%)	10, 25% (11%, 39%)	137, 34% (30%, 39%)
Total	**53, 27% (21%, 34%)**	**64, 40% (32%, 47%)**	**152, 21% (18%, 24%)**	**46, 15% (11%, 19%)**	**46, 29% (22%, 36%)**	**28, 14% (9%, 19%)**	**62, 22% (17%, 27%)**	**451, 22% (20%, 24%)**
P value	**0.067**	**0.050**	**0.007**	**0.001**	**0.000**	**0.014**	**0.879**	**0.000**
Health-related claims								
Germany	7, 23% (8%, 38%)	8, 31% (13%, 49%)	25, 17% (11%, 24%)	12, 21% (11%, 32%)	8, 23% (9%, 37%)	3, 8% (-1%, 17%)	19, 28% (17%, 38%)	82, 21% (17%, 25%)
Netherlands	5, 13% (2%, 24%)	16, 44% (28%, 615)	36, 23% (16%, 30%)	13, 20% (10%, 29%)	13, 43% (25%, 61%)	3, 8% (-1%, 18%)	17, 32% (19%, 45%)	103, 25% (21%, 29%)
Spain	7, 23% (8%, 39%)	23, 58% (42%, 73%)	31, 24% (17%, 31%)	9, 12% (4%, 19%)	4, 13% (1%, 24%)	8, 21% (8%, 34%)	18, 32% (19%, 44%)	100, 25% (21%, 29%)

	Potatoes, bread, rice, pasta or other starchy carbohydrates	Dairy or dairy alternatives	Foods high in fat and/or sugar	Beans, pulses, fish, eggs, meat and other protein	Fruit and vegetables	Composite foods	Miscellaneous	Total
Slovenia	23, 41% (28%, 54%)	12, 40% (22%, 58%)	37, 21% (15%, 28%)	3, 6% (-1%, 12%)	4, 15% (1%, 30%)	3, 15% (-1%, 31%)	21, 35% (23%, 47%)	103, 25%, (21%, 29%)
UK	15, 40% (24%, 55%)	16, 53% (35%, 72%)	43, 31% (24%, 39%)	16, 33% (19%, 46%)	24, 67% (51%, 82%)	15, 22% (12%, 32%)	11, 28% (13%, 42%)	140, 35% (31%, 40%)
Total	**57, 29% (23%, 36%)**	**75, 46% (39%, 54%)**	**172, 23% (20%, 26%)**	**53, 18% (13%, 22%)**	**53, 33% (26%, 41%)**	**32, 16% (11%, 21%)**	**86, 31% (25%, 36%)**	**528, 26% (24%, 28%)**
P value	**0.018**	**0.226**	**0.083**	**0.004**	**0.000**	**0.197**	**0.894**	**0.000**

Prevalence of health and nutrition claims by country (Table 4.3)

Overall, 26% of foods (95% CI 24%, 28%) carried at least one health-related claim. There were significant differences between countries (X^2 = 24.6, 4df, p<0.001): the UK had the highest prevalence of health-related claims where 35% (95% CI 31%, 40%) of foods carried a health-related claim. In the Netherlands, Spain, and Slovenia 25% of foods carried a health related claim. Germany had the lowest prevalence of claims (21%, 95% CI 17%, 25%). More than a third (34%) of foods carrying health claims also carried a nutrition claim. Within the UK, just 3 of the 45 foods carrying a health claim did not also carry a nutrition claim, whereas in the Netherlands half of the foods carrying a health claim also carried a nutrition claim.

The proportion of foods carrying a health claim also varied by country (X^2 = 12.1, 4df, p<0.05); Spain had the lowest proportion of foods with a health claim (7%, 95% CI 5%, 10%) and the Netherlands had the highest prevalence of health claims (14%, 95% CI 11%, 18%).

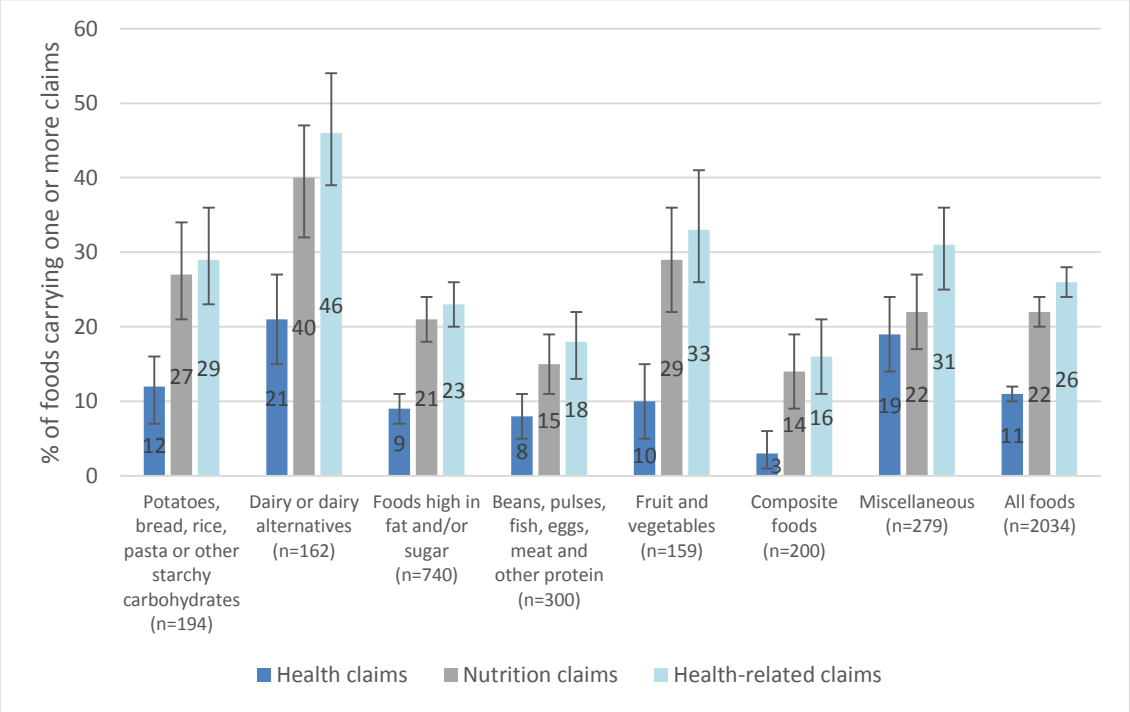
Nutrition claims were more prevalent than health claims: 22% (95% CI 20%, 24%) of foods carried a nutrition claim whereas 11% (95% CI 10%, 12%) of foods carried a health claim. There was greater country variation in the prevalence of nutrition claims than observed for health claims. The proportion of foods carrying a nutrition claim was similar in Germany (18%, 95% CI 14%, 21%), the Netherlands (18%, 95% CI 14%, 21%), and Slovenia (19%, 95% CI 15%, 23%). A greater proportion of foods in Spain (23%) and the UK (34%, 95% CI 30%, 39%) carried at least one nutrition claim. The country differences were statistically significant (X^2 = 47.7, 4df, p<0.001).

Types of health and nutrition claims

The most prevalent claim type was nutrient content claims - 20% (95% CI 18%, 21%) of foods carried at least one nutrient content claim, 2% (95% CI 2%, 3%) of foods carried a nutrient comparative claim, and 4% of foods carried a health-related ingredient claim. With regard to

health claims, general health claims were observed on 7% (95% CI 6%, 8%) of foods, and nutrient and other function claims were found on 5% (95% CI 4%, 6%) of foods. Less than 1% of foods carried a reduction of disease risk claim (0.6%, 95% CI 02%, 0.9%) or a children's development and health claim (0.7%, 95% CI 0.4%, 1.1%).

Figure 4.3 Prevalence of health-related claims by food group



Types of products carrying health and/or nutrition claims (Figure 4.3)

The proportion of foods that carried a health-related claim differed by food group: Dairy and alternatives had the highest proportion – 46% (95% CI 39%, 54%), whereas Composite foods had the lowest proportion of foods carrying a claim (16%, 95% CI 11%, 21%).

Nutrition claims were most prevalent in the Dairy and alternatives group where 40% (95% CI 32%, 47%) of foods carried a nutrition claim. A lower proportion of Beans, pulses, fish, eggs, meat and other protein (15%, 95% CI 11%, 19%) and Composite foods (14%, 95% CI 9%, 19%)

carried a nutrition claim. The proportion of foods carrying at least one health claim ranged from 3% (95% CI 1%, 5%) of Composite foods to 21% (95% CI 15%, 27%) of Diary and alternatives.

References to nutrients (Table 4.4)

The nutrient most commonly referred to in nutrition claims was fat (e.g. “low in fat”), which was referenced in 22% of all nutrition claims and 8% of all health claims. More than a third (34%) of fat references were found on products from the UK. References to vitamins were seen in 22% of the nutrition claims, a quarter of which referred to the Vitamin C content.

With regard to health claims, vitamins and/or minerals were referred to in 16% of all health claims. Within countries this ranged from 5% of claims (4 claims) in the Netherlands to 28% of claims (24 claims) in the UK. References to unspecified nutrients (e.g. “complete nutrition”) were common in most countries, particularly in Slovenia (59% of Slovenian claims, 52 claims) and Germany (41% of German claims, 34 claims) but were less common in the UK, (27% of UK claims, 23 claims).

Most of the health-related claims (11 claims) that referenced phytosterols and plant stanols (e.g.”…contain plant stanols, proven to lower cholesterol”) were found in the UK (9 claims), of the remaining 4 countries just Slovenia and Spain had a single plant stanol/phytosterol claim. Many of the fibre references were also observed on products from the UK (33 claims) and Spain (24 claims), whereas only 5 claims in Germany and 13 claims in both the Netherlands and Slovenia referenced Fibre.

Within the UK, 20% (81 claims) of health-related claims referred to fats, similarly in Spain (20%, 54 claims), and Germany (24%, 53 claims), whereas fewer products in the Netherlands (11%, 26 claims) and Slovenia (10%, 23 claims) made such references.

Just 3% of health-related claims (43 claims) referenced protein and there was little variation between countries; ranging from 4 claims (2%) in Slovenia to 11 claims in the UK (3%). Similarly, sodium and/or salt was referenced in just 1% of claims (2 claims) in Slovenia to 4% (16 claims) of claims in the UK.

Prevalence of health and nutrition claims by function/disease (Table 4.5)

There were 185 nutrient and other functions claims. Whilst there were some claims (18%, 95% CI 13%, 24%) that could not easily fit into a single ICF group (e.g. "important for healthy growth and development"), the remaining claims were categorised accordingly.

The most common function that these claims referred to was to those of the digestive, metabolic, and endocrine systems - 40% (95% CI 33%, 47%). Of these, claims that referred to general metabolic functions were most common, for example "...vitamins B are important for the energy-yielding metabolism". Claims referring to digestive functions (e.g. "fibre helps maintain a healthy digestive system" on a Fruit and vegetable product in the UK) were also common (10%, 95% CI 6%, 15%).

Claims that referred to functions of the cardiovascular, hemotological, immunological and respiratory systems were the second most common type (15%, 95% CI 10%, 20%), particularly claims that referred to the immunological system (9%, 95% CI 5%, 13%) such as "zinc helps maintain a healthy immune system" and heart functions (5%, 95% CI 2%, 8%) such as "omega-3 EPA and DHA are added which contribute to the normal function of the heart".

Mental functions were referred to in 11% (95% CI 96%, 16%) of claims, most of these claims referred to energy and drives, for example "Contributes to the reduction of tiredness and fatigue". Neuro-musculoskeletal and movement-related functions were referenced in 10% (95% CI 6%, 15%) of nutrient and other function claims, most of these claims referred to

functions of the joints and bones, this includes claims such as “protein contributes to the maintenance of normal bones” and “Vitamin D and Calcium for strong bones”.

Table 4.4. References to nutrients in health and nutrition claims [109]

Nutrient	**Nutrition claim (n)**	**% of all nutrition claims**	**Health claim (n)**	**% of all health claims**
Energy	40	5%	1	0%
Protein	35	4%	8	2%
Carbohydrates	109	13%	14	4%
- Of which sugars	100	12%	2	1%
Fat	206	24%	31	8%
- Total fat	127	15%	5	1%
- Saturated fat	7	1%	3	1%
- Unsaturated fat	50	6%	23	6%
- *Omega-3 fatty acids*	33	4%	15	4%
Fibre	74	9%	14	4%
Sodium / Salt	35	4%	0	0%
Vitamins and/or minerals	305	35%	64	16%
- Vitamins and Minerals	2	0%	3	1%
- Vitamins (any)	187	22%	38	10%
- *Vitamin C*	47	5%	8	2%
- *Vitamin D*	15	2%	9	2%
- *Vitamin E*	19	2%	5	1%
- *Other specified vitamins*	55	6%	11	3%
- *Unspecified vitamins*	51	6%	5	1%
- Minerals (any)	116	13%	23	6%
- *Calcium*	55	6%	13	3%
- *Iron*	21	2%	3	1%
- *Other specified minerals*	26	3%	6	2%
- *Unspecified minerals*	14	2%	1	0%

Nutrient	Nutrition claim (n)	% of all nutrition claims	Health claim (n)	% of all health claims
Probiotics	23	3%	2	1%
Phytosterols/stanols	6	1%	5	1%
Whole products	0	0%	84	21%
Unspecified nutrient	4	0%	141	36%
Other nutrients	27	3%	9	2%
Ingredients that aren't nutrients	1	0%	19	5%
- Herbs	0	0%	12	3%
- Seeds	0	0%	3	1%
- Whole grain / Whole wheat / Whole foods / Whole meal	1	0%	2	1%
Total	**865**	**100%**	**392**	**100%**

Table 4.5. Nutrient and other function claims by ICF code

ICF chapter		**No. of claims**	**% of claims (95% CIs)**
Mental Functions	Global psychosocial functions	4	2.2% (0.0, 4.3)
	Energy and drive functions	8	4.4% (1.4, 7.4)
	Sleep functions	2	1.1% (-0.4, 2.6)
	Specific mental functions	1	0.5% (-0.5, 1.6)
	Higher-level cognitive functions	1	0.5% (-0.5, 1.6)
	Total	**20**	**11.0% (6.4, 15.6)**
Sensory Functions and Pain	Seeing and related functions	1	0.5% (-0.5, 1.6)
	Total	**1**	**0.5% (-0.5, 1.6)**
Voice and Speech Functions	Voice functions	4	2.2% (0.0, 4.3)
	Total	**4**	**2.2% (0.0, 4.3)**
Functions of the cardiovascular, haematological, immunological and respiratory systems	Heart functions	9	4.9% (1.8, 8.1)
	Blood vessel functions	1	0.5% (-0.5, 1.6)
	Immunological system functions	16	8.8% (4.6, 12.9)
	Functions of the respiratory system	1	0.5% (-0.5, 1.6)
	Total	**27**	**14.8% (9.6, 20.0)**
Functions of the digestive, metabolic and endocrine systems	Digestive functions	19	10.4% (6.0, 14.9)
	Defecation functions	5	2.7% (0.3, 5.1)
	Weight maintenance functions	14	7.7% (3.8, 11.6)

ICF chapter		No. of claims	% of claims (95% CIs)
	General metabolic functions	27	14.8% (9.6, 20.0)
	Water, mineral and electrolyte balance functions	6	3.3% (0.7, 5.9)
	Endocrine gland functions	2	1.1% (-0.4, 2.6)
	Total	**73**	**40.1% (32.9, 47.3)**
Genitourinary and reproductive functions	Urinary excretory functions	1	0.5% (-0.5, 1.6)
	Sexual functions	2	1.1% (-0.4, 2.6)
	Total	**3**	**1.6% (-0.2, 3.5)**
Neuro-musculoskeletal and movement related functions	Functions of the joints and bones	15	8.2% (4.2, 12.3)
	Muscle endurance functions	4	2.2% (0.0, 4.3)
	Total	**19**	**10.4% (6.0, 14.9)**
Functions of the skin	Functions of the skin	2	1.x% (-0.4, 2.6)
	Functions of the hair and nails	1	0.5% (-0.5, 1.6)
	Total	**3**	**1.6% (-0.2, 3.5)**
Others	Functions related to the digestive system: Teeth	15	8.2% (4.2, 12.3)
	Functions of the haematological and immunological systems: Antioxidants	8	4.4% (1.4, 7.4)
	Growth	9	4.9% (1.8, 8.1)
	Total	**32**	**18.1% (12.5, 23.8)**
TOTAL		**185**	**100.0%, 5.2% (4.2, 6.2)**

Discussion

Main findings

Overall, 26% (95% CI 24%, 28%) of the foods sampled carried at least one health-related claim. The prevalence across the five countries ranged from 21% (95% CI 17%, 25%) in Germany to 35% (95% CI 31%, 40%) in the UK. Nutrition claims were found on 22% (95% CI 20%, 24%) of products and health claims on 11% (95% CI 10%, 12%). The prevalence of claims differed by food group - almost half of the dairy and alternatives products carried a health-related claim (46%, 95% CI 39%, 54%) compared to just 16% (95% CI 11%, 21%) of Composite foods.

Comparison to other literature

Comparisons to previous studies are difficult due to the differences in sampling methods, the definitions and categorisations used, and the time of data collection.

We found a higher proportion of foods that carry a health claim (11%, 95% CI 10%, 12%) than the FLABEL study. The FLABEL study was the first European cross-country survey of nutrition labelling and found that the prevalence of front-of-pack nutrition claims ranged from 12% in Estonia to 37% in Ireland and Portugal. The prevalence of health claims was very low, just 4% of foods carried health claims on the FOP and 2% carried health claims on the back-of-pack. [28]. There are a number of potential causes for these differences in results. The FLABEL study only examined claims visible on the front of pack (whereas we considered all sides of the pack visible without opening the product). The FLABEL study only examined five food categories: sweet biscuits, breakfast cereals, pre-packed chilled ready meals, carbonated soft drinks, and yoghurts, whereas our sampling frame included most food categories. Furthermore, the FLABEL data collection was conducted in 2008-2009, prior to when many aspects of the regulation on health and nutrition claims came into effect [38], whereas in the current study the data was collected in June-September 2013.

A more recent study conducted in the UK also found a low proportion of products carried health-related claims. Van Camp and Hooker [133] estimated the prevalence of Front-of-Pack Guideline Daily Amounts (GDAs) and Traffic Light Labelling prevalence on pre-packaged foods released in the UK in 2008. They used the Mintel Global New Product Database (GNPD) to compare the FOP nutrition labelling in food groups identified by the UK FSA as ideal for FOP labelling ('target' food groups), versus non-target groups. The GNPD is a database of products collected from a variety of sources and retail outlets. The study also measured the prevalence of 'other' types of FOP labelling, this referred to 'two or more nutritional facts, claims, or statements on the front of package…' but not containing GDAs or Traffic Light Labelling (page 582, [133]). This loosely fits the definition of health-related claims that I use in this study. They found that 5% of target foods (hot cereal, cold cereal, pastry dishes, pizza, prepared meals, and sandwiches, n=400) carried 'other' FOP nutritional labelling compared to 3% of 'non-target' foods (bread, cakes/pies/sweet goods, savoury biscuits, sweet biscuits, instant noodles/pasta/rice, and meal kits, n=501). This low rate may be due to the study's definition of claims and the focus on FOP labelling.

We reported a lower prevalence of health-related claims than that reported in an Irish study of foods that are commonly consumed where 47% of foods carried a nutrition claim and 18% carried a health claim. [111]. The 'commonly eaten foods' were identified in another study [137] which found that meats, breads, potatoes, milk and yoghurt, cakes and biscuits, breakfast cereals, spreads, and vegetables make up 75% of the overall average energy intake. Four supermarkets in Dublin, Ireland were visited and 1880 food labels (across eight food categories) were examined. However, this sample of foods consisted of a smaller number of food categories and was designed to represent the foods most commonly consumed rather than a representation of all foods available to purchase.

In the current study we found that 40% of Dairy and alternatives carried a nutrition claim, and 21% carried a health claim, whereas the French Observatory of Food Quality (OQALI) study of commonly consumed dairy products found that 22% of dairy products carried at least one nutrition claim and 10% carried a health claim [135]. In the French OQALI study, products were identified through examining population-level intake data combined with sales data. In total, 1646 dairy products were collected from different brand types; national brands, retailer brands, economy brands, and discount brands. These differences may also be due to the use of sales data.

A recent study in Slovenia measured the impact of introducing sales data when estimating the proportion of foods that carry claims (i.e. weighting the database so that foods that are more commonly purchased are given more prominence than foods with lower sales). Pravst and Kusar [134] examined health-related claim prevalence in the same eight food categories identified by Lalor et al [111] , plus the following food categories; processed seafood, ready-made products, vegetable oils, and plant-based imitations of milk and diary. In this study, the researchers visited four food stores (one large supermarket, two neighbourhood stores, and one discounter store) and sampled all pre-packaged foods in the categories mentioned.

In total, 6341 foods were identified and sales data were obtained for 81% of the foods. This subset of the data was used to estimate the prevalence of pre-packaged foods carrying health-related claims, and then separately this measure was weighted by the sales data to provide an estimate of consumer exposure to claims. They found that 39% of foods carried a health-related claim, when weighted by sales data this increased to 46%. As with the results presented in this chapter, Pravst and Kusar also found that nutrition claims (37% of foods, non-weighted data) were more common than health claims (13% of foods, non-weighted data). There were some similarities between this study and our prevalence estimates for Slovenia. We also found that in Slovenia 13% (95% CI 9%, 16%) of products carried a health

claim, but we found a lower proportion of foods that carried a nutrition claim (19%, 95% CI 15%, 23%, versus 37%). These differences may be due to the differences in sampling methods and specifically the store types used for data collection. In the current study we sampled 250 products from a supermarket, and 75 products from a neighbourhood store, and 75 products from a discounter store, whereas Pravst and Kusar examined all foods from the selected food categories in each of the store types.

Similarly, our findings from the UK are similar to those reported in an earlier study I conducted where foods where sampled from a food retailer's website [136]. This study may be the most comparable due to the similarities in the claim definitions and the sampling methods. In that paper, I estimated the UK prevalence of health-related claims by using a retailer's website to randomly select products for purchase (rather than purchasing all of the products from selected food categories). In that study I found that 32% (95% CI 28%, 37%) of products carried a health-related claim, 29% (95% CI 25%, 34%) carried a nutrition claim and 15% (95% CI 11%, 18%) carried a health claim. In the current study, we found that 35% (95% CI 31%, 40%) of products carried a health-related claim, 34% (95% CI 30% 39%) carried a nutrition claim, and 11% (95% CI 10%, 12%) carried a health claim.

Strengths and limitations

A potential limitation of this study is that the selection of the five countries was based on the experience and availability of the researchers involved with the CLYMBOL product rather than, for example, food labelling practices. This may have introduced bias towards countries with strong food labelling practises as it's possible that such countries may be more likely to have participated in the CLYMBOL project.

One of the limitations of this study is that two different methods were used to sample foods, the store-list method and the floor-plan method (both described in Chapter 3). Of the 15

stores used for data collection, 11 of the stores provided the researchers with a stock list. Where the store list was used we do not have a record of how accurate or representative the list was in relation to what was available to purchase on the day(s) of the visit. The remaining four stores did not provide a stock list therefore the floor-plan method was used instead. The Netherlands, Spain, and Slovenia all used the store-list method and all found an overall prevalence rate of 25%, the UK data was collected solely using the floor-plan method and found a higher proportion of products carrying claims (35%). However, this was largely due to the higher prevalence of nutrition claims in comparison to the other countries and the findings are similar to the study where foods where sampled from a food retailer's website [136] (where the method of sampling products more closely resembled the stock list approach), therefore the results reported here are more likely to reflect genuine country differences in the prevalence of health-related claims rather than arbitrary differences due to variation in methods.

A high proportion of products that were sampled were categorised as Foods high in fat and/or sugar (36%, 95% CI 34%, 38%). This may suggest that the sampling method was bias towards these foods. This may be due to areas that had large proportions of unpackaged foods (such as delicatessen and/or fruit and vegetable areas) were excluded from the sampling frame. These areas may be less likely to contain pre-packaged Foods that are high in fat and/or sugar.

Another potential source of bias may be the accuracy of the data collectors' estimates of the number of eligible products within each area. The in-store sampling method involved the data collectors making estimates of the number of products in each section of the store. Numbers were then randomly generated to represent sections and products within each section (see Appendix C for more details). If a researcher consistently underestimated the number of products in a section then this would inadvertently exclude some foods from the sampling frame. The bias would be that products on the bottom shelf (or end of the aisle) were less

likely to be sampled. Therefore the data collectors were advised to alternate the order of the shelf counting, so that when a section estimate was smaller than the number of products on the shelf then either the top shelf or bottom shelf (depending on the 'starting' position') will be less likely to be sampled.

A limitation of the store plan method is that foods that appear in more than one location (e.g. items that have additional promotional displays or areas) have an increased probability of being chosen than foods that are only available in a single location in a store. To account for this data extractors were instructed to replace any duplicate products with a new randomly selected product, however we do not have a record of how many times (if at all) this occurred.

One of the strengths of this study was that researchers from each of the five countries conducted the data collection. This was advantageous as claims in other languages were observed and translated by native speakers rather than relying upon online language translators which may miss any culturally specific nuances. All of the researchers involved in the study used the same materials (Appendix C) and they were encouraged to raise any queries or issues and any responses were shared with all of the researchers.

Additional steps were taken to check that the data were being extracted, entered, and categorised in a similar fashion across the five countries. For example once the data from the first ten products had been extracted, the databases from each country were sent to me to check for any errors. Also, the health-related claim categorisations were verified by three of the researchers (Dr Hieke, Professor Pravst, and Professor Rayner). However, there was not a defined process to check how well the protocol had been adhered to. There was one known instance where the protocol was not followed. The data collectors were instructed to retain the food labels of all purchased products. This would allow other researchers to analyse the food labels at a later date and/or for the food labels to be used in other studies. However, due

to space limitations, after extracting the data from the food labels, the Spanish team took photographs of the food labels with health-related claims and discarded the food labels.

These issues notwithstanding, another strength of this study is that efforts were made to make the methods as standardised as possible. The materials used are available on request so that future studies may replicate the methods and use this study as a baseline to which to compare.

Summary

In this chapter I presented the results of a five country cross-sectional survey designed to estimate the prevalence of health-related claims on pre-packaged foods available to purchase. Whilst there were some country differences, overall 26% (95% CI 24%, 28%) of foods carried a health-related claim, and a greater proportion of foods carried a nutrition claim (22%, 95% CI 20%, 24%) compared to health claims (11%, 95% CI 10%, 12%). There were differences between food groups, for example, Dairy and alternatives carried significantly more claims than Composite foods.

In the next chapter I use the health-related claims prevalence described in Table 4.3 and the corresponding nutritional data recorded from the food labels to assess the nutritional quality of the foods carrying health-related claims compared to foods that do not carry any claims. To do this I compare the mean levels, per 100g, of energy, protein, carbohydrates, total sugars, total fat, saturated fat, fibre, and sodium. As shown in this chapter, the prevalence of health-related claims differs by food group, therefore two sets of regression analyses are also conducted: one which adjusts for food group and one which does not.

I then apply a nutrient profile model (the FSANZ NPSC) to examine the impact of restricting health-claims with a nutrient profile model. In this scenario, only foods that pass the FSANZ

NPSC are permitted to carry claims. The mean levels of nutrients of foods that carry health-related claims and pass the FSANZ NPSC are then compared to the mean levels of nutrients of foods that do not pass the FSANZ NPSC (i.e. regardless if they carry a health-related claim). The regression analyses described above are then repeated.

5. The nutritional quality of foods with and without health-related claims

Introduction

In the previous chapter I presented the results of a multi-country, cross-sectional survey of health-related claims on pre-packaged food labels. The main findings were that 26% (95% CI 24%, 28%) of pre-packaged foods carried health-related claims and the prevalence differed by food group, for example; 46% (95% CI 39%, 54%) of Dairy and alternatives carried a claim compared to 16% (95% CI 11%, 21%) of Composite foods. In the present chapter I use the nutritional data collected from that survey to compare the mean levels of energy, protein, carbohydrates, total sugars, saturated fat, total fat, fibre, and sodium for foods that carry health-related claims and foods that do not.

The analyses I presented in this chapter were also published in the European Journal of Clinical Nutrition [110]. The methods for creating the database upon which the current analyses were conducted were described in Chapter 3 (e.g. definitions, sampling methods, pilot studies, and data extraction and categorisation). This chapter contains the methods for preparing the data for the analyses presented in this chapter.

Background

Role of food labels and health-related claims

The results of the systematic review (Chapter 2) suggest that health-related claims on food labels have a substantial effect on dietary choices. Results from the meta-analyses of 17 studies found that foods carrying health-related claims were 75% more likely to be chosen than identical foods that do not carry health-related claims (OR 1.75, 95% CI 1.60, 1.91).

Health-related claims may help consumers identify healthier foods more easily [138-140], or they may have a negligible effect on the overall healthiness of purchases [141] or they may hinder this process [51], dependent upon whether health-related claims are good cues for healthy foods.

Research conducted in the US found that products carrying health claims could lead to bias. A product carrying a health claim was more likely to be perceived by consumers as having additional positive attributes that were not referenced in the health claim ('the halo effect') or that were inappropriate for the product ('magic-bullet effect'). The presence of a health claim also led to consumers reducing their reliance upon other, more detailed, sources of information such as the nutritional information panel [51].

The Regulation (EC) 1924/2006 on nutrition and health claims made on foods, states that

"…claims shall not:

(a) be false, ambiguous or misleading;
(b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;
(c) encourage or condone excess consumption of a food;…"

(page 11, General principles for all claims [38]).

One interpretation could be that a health-related claim could be deemed misleading if the food on which the claim is made has a less favourable nutritional composition compared to similar products without such claims or if the food carrying a claim has unfavourable levels of other nutrients.

Within the EU, there are guidelines regarding the use of nutrition content claims (e.g. 'low in…', 'source of…') and nutrient comparative claims (e.g. 'reduced…', 'higher in…') claims. For example, in order to carry a 'low fat' claim a food must not contain more than 3g of fat per 100g for solid foods (or 1.5g per 100g for liquids). In order to carry a nutrient comparative claim such as 'reduced fat' the food must contain 30% less of the specified macro-nutrient, 25% less in the of salt/sodium, or 10% for micro-nutrients, compared to a similar product.

In order to carry a positive nutrient comparative claim (e.g. 'higher amount of fibre'), foods must first be eligible to carry a nutrient content claim for that nutrient. For example, the nutrient threshold to use the claim 'source of fibre' would be 3g per 100g, or 6g per100g to claim that a food is 'high fibre'. In addition to this, the food must also contain 30% more fibre than a similar product. Similar rules exist for energy claims, saturated fats, sugars, sodium, fibre, and protein *[38]*, but these are all nutrient-specific rules – there is no criterion for the overall nutritional quality of the food.

Nutrient profiling is "…the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health." [44]. Nutrient profiling evaluates the data for more than one nutrient and/or food component (e.g. amount of fruit and vegetables) of an individual food in order to make an evaluation of the food's nutritional quality. Nutrient profile models have been used for a range of purposes including, within the UK to regulate TV advertising to children [45].

In Regulation (EC) 1924/2006, the European Commission stated that nutrient profile models shall be used to regulate health-related claims "…to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet." (page 4, *[38]*). However, the European Commission has not introduced a nutrient profile model.

In December 2016, the European Commission announced that it is evaluating Regulation (EC) 1924/2006. As part of the evaluation the European Commission will investigate whether nutrient profile models are required for the Regulation to work effectively and assess any impacts of failing to adopt a nutrient profile model [46].

Nutritional quality of foods carrying health-related claims

There has been little research on the difference in nutritional quality between pre-packaged foods carrying health-related claims and those that don't, particularly across food groups. Mostly these studies have been conducted outside Europe.

Previous studies have compared the nutritional quality of foods carrying health-related claims to the equivalent amount of fruit and/or vegetables [142], or to foods that are high or low in selected nutrients [143], or to foods that are and are not advertised to children [144], or examined product ranges (as opposed to individual products/foods) [145], or only examined one particular type of claim on a specific food item (e.g. health symbols on baby foods [146].

Where other studies have compared the nutritional quality of foods carrying claims and foods that do not, the outcome measure was not the difference in the average levels of nutrients. For example, a study conducted in the US [143] measured how likely it was for foods carrying health-related clams to pass the United States' Food and Drug Administration (US FDA) nutrient profile model [147].

In an earlier study, I examined the nutritional quality of foods carrying health-related claims compared to foods that do not carry claims, however that study only examined products from one store, in one country [136].

Research questions

In this chapter I compare the nutritional quality, measured by the mean levels of eight nutrients, of foods that carry health-related claims and foods that do not. The analyses uses the nutritional data collected from a multi-country, cross-sectional survey of health-related claims on pre-packaged foods (described in Chapters 3 and 4). The research questions for this chapter are:

- Do foods that carry a health-related claim have a better nutritional composition than those that do not?
- Are there any differences in nutritional quality according to the type of health-related claim (i.e. health claims compared to nutrition claims)?
- Are there any differences in nutritional quality by food group?
- Are there any country differences in the proportion of foods that pass a nutrient profile model (the FSANZ NPSC)?

Methods

The background (e.g. definitions, sampling methods, pilot studies, and data extraction and categorisation) on this database is described in Chapter 3. This section contains the methods for preparing the data for the analyses presented in this chapter.

Mean levels of nutrients

The following nutritional information was recorded from the food label: energy, protein, carbohydrate, total sugars, fat, saturated fat, fibre and sodium. In this chapter I compare the mean levels (per 100g, as consumed) of these nutrients.

The serving size information was also recorded when available from the food label, however this information was problematic as it was often not provided by manufacturers and many foods could have multiple serving sizes (e.g. for a child or an adult, or as a snack or as part of meal). Therefore a 100g base was chosen for the comparison of the mean levels of nutrients.

Examining the nutrients in isolation from one another is useful as it gives an overall picture of any differences in the average levels of each nutrient in the current food supply. However, examining the mean amounts does not allow us to assess the overall nutritional composition

of individual products or whether the composition is more favourable in foods carrying claims. Foods carrying claims may have a favourable level of one nutrient but unfavourable levels of another nutrient (e.g. low in fat but high in sugar). Therefore, I also apply a nutrient profile model to compare the overall nutritional quality of foods that carry health-related claims and foods that do not.

The Food Standards Australia New Zealand Nutrient Profiling Scoring Criterion (FSANZ NPSC)

The FSANZ NPSC was implemented in Australia and New Zealand in Standard 1.2.7 – Nutrition, health and related claims [47]. In the standard it states that foods must pass the FSANZ NPSC to be eligible to carry a health claim. The FSANZ NPSC is applicable to health claims – foods carrying nutrition claims or nutrient indicator systems (such as Australia's Health Star Rating System [148]) do not need to pass the model. The standard was introduced in January 2013 and food manufacturers were given three years to comply with the new law.

The FSANZ NPSC is based upon the UK's broadcasting regulator's (the Office of Communications, also known as 'Ofcom') nutrient profile model which is used to regulate TV advertisement of foods to children. In order to run a food advertisement during programmes with a large child audience, the foods advertised must pass the nutrient profile model [45].

THE FSANZ NPSC scores foods on their levels of energy, saturated fat, total sugars, and sodium per 100g. The scoring thresholds are specific to each nutrient. A lower score indicates a lower amount. The scores for energy, saturated fat, total sugars, and sodium are summed to create the 'Baseline points'. Scores are also given for the food's fruit and vegetable content ('V points'), protein levels ('P points') and fibre levels ('F points') per 100g. The overall score is achieved by subtracting these scores from the Baseline points. This score is assessed using the

FSANZ NPSC scoring thresholds, if the score is higher than the threshold then it fails the model and thus cannot carry a health-related claim.

The FSANZ NPSC is a category-specific nutrient profile model. The FSANZ NPSC has three food categories; Category 1 foods refers to beverages, Category 2 foods refers to any food that is not a Category 1 or 3 food, and Category 3 foods refers to cheese, and (edible) oils, fats, and spreads.

The scoring thresholds are different for each Category. In order for a beverage/Category 1 food to pass it must score ≤ 0 points, whereas cheeses (or oils, margarines, butter)/Category 3 foods must score ≤ 28 points, and other foods/Category 2 foods must score ≤ 3 points.

As well as passing the FSANZ NPSC, there are additional nutritional criterion that the food must pass depending on the type of health claim under consideration. In Australia and New Zealand health claims are categorised as 'general health claims' or 'high level health claims'. The latter refers to claims that reference serious diseases (and biomarkers of serious diseases) such as coronary heart disease (CHD), cancers, etc. Some 'high level' claims have additional requisites, for example, to carry a health claim that refers to the effect of high fruit and vegetable intake on the (reduced) risk of CHD, the product carrying the claim must not be a fruit juice, and must contain at least 90% fruit or vegetable (Schedule 2, [47]).

The rules for 'general health claims' are more numerous (Schedule 3, [47]). For example, to carry a health claim that refers to calcium effect on teeth, bone, muscle, blood, digestion, cell division, and/or normal growth development, the food must meet the conditions for carrying a nutrient content claim for calcium (25% of the RDI).

In this thesis, the model applied to the database of 2000 foods collected in five European countries, does not take these additional rules for general or high level claims into account. This is due to the differences in health claim categorisation in the health-related claim

database and in Standard 1.2.7. Also, many of these rules refer to micronutrients which were not collected from the food label.

The model was applied to the database using the statistical Software Stata [75]. A Stata DO-file was written for the model which was checked for errors by another researcher.

Additional nutritional data source(s)

In order to apply the FSANZ NPSC to the database of foods the following nutritional information, per 100 grams, is required:

- Energy (kJ)
- Saturated fat (g)
- Total sugars (g)
- Sodium (mg)
- Protein (g)
- Fibre (g)
- Fruit and vegetables
- For cheeses only – calcium (mg)

At the time of data collection for the CLYMBOL study (July-September 2013) the provision of nutritional information was only compulsory on foods that carried a health-related claim. The findings from the FLABEL study [28] suggested that there may be some variation between countries in regards to the information provided on the food label. Furthermore, the FSANZ NPSC criterion states that cheeses, oils, butters, margarines, and other spreads must contain more than 320mg calcium per 100g, otherwise the food should be considered as a food item (which has a lower threshold). Not all foods contained information on all of the nutrients

required to apply the FSANZ NPSC. Therefore a food compositional table was used to supplement the dataset.

The UK Nutrient Databank is a database of approximately 8000 foods and contains data for a broad range of nutrients for each food. The Nutrient databank is an excel version of the McCance and Widdowson Composition of Foods tables [119]. The data is used to monitor the nutritional quality of the UK population diet through the NDNS [10].

Each of the 2034 foods sampled was matched to a similar, often non-branded, food in the UK Nutrient Databank, for example the drink Appletiser would be matched to 'Carbonated apple juice beverage'. The matching was initially conducted by local researchers in each country. I then assessed how well the foods were correlated by conducting Pearson correlations between the nutritional data recorded from the food label and the corresponding data of the matched product in the UK Nutrient Databank. Any outliers were examined and, where possible, I identified a more appropriate (i.e. a food with more similar nutritional composition) substitute product in the UK Nutrient Databank.

Where there was partial nutritional data on the food label, the nutritional data from matched product in the UK Nutrient Databank was merged with the food label data so that the food label data always took precedence over the data of the matched product. These supplemented data were only used for the application of the nutrient profile models – the data are not considered when examining the mean levels of nutrients. For comparisons of the mean levels of nutrients each nutrient was examined separately regardless of whether the amount of other nutrients was given – for example a product would still be included in the comparison for the mean levels of energy even if the food label did not include data on any other nutrients.

Assessing the appropriateness of using non-country specific food composition tables

Prior to the data collection phase the use of country-specific food composition tables was explored. However, as these databases were not freely available and due to time and budget constraints it was decided that the UK Nutrient Databank would be used for all countries.

Within the CLYMBOL project team, one country already had access to and experience with, a local food composition table. Each product sampled in Slovenia was also matched to a similar food in the Slovenian OPEN platform for Clinical Nutrition (OPEN DB) [149, 150]. The Slovenian OPEN DB is a food composition table for Slovenian foods and has been validated as an accurate representation of the food supply in Slovenia [150]. The same instructions and guidance was given as for the original matching exercise (Appendix C) to ensure a consistent approach. Pearson's correlations were conducted to see how well correlated the data from the Slovenian DB matched product was to the food label data and the equivalent matched product in the UK Nutrient Databank.

Statistical analyses

All statistical analyses were conducted in Stata V11 [75].

Pearson's correlation tests were conducted to test how well correlated the food label data were to the matched products in the UK Nutrient Databank, and the Slovenian OPEN DB. Cohen's Kappa and the standard error was used to measure the percentage agreement in the way foods are classified by the FSANZ NPSC when the UK Nutrient Databank was used to supplement the missing nutritional data, and when the Slovenian OPEN DB was used. Kruskal–Wallis tests were conducted to test whether there was an association between food category and the presence of health-related claims and the nutritional values.

The mean levels, per 100g, were calculated for the following nutrients: energy, protein, carbohydrate, total sugars, fat, saturated fat, fibre and sodium. As the nutrient data were not normally distributed – with large spikes at zero for many nutrients - a non-parametric test was necessary. The Mann-Whitney two sample test was conducted to determine if the differences in nutrient levels between foods carrying and not carry health-related claims were statistically significant at the $p = 0.05$ level. In order to assess whether differences were due to confounding by food category, two sets of regression analyses were also conducted – one set of results (Model 2) adjusted for food group and one set of results did not (Model 1). The unadjusted model is included for comparison to the results of the Mann-Whitney tests.

The impact of using the FSANZ NPSC to regulate health-related claims was modelled to see whether the use of a nutrient profile would improve the average nutritional quality of foods that carry claims through calculating the mean level of nutrients for foods that carry health-related claims/health claims/nutrition claims and also pass the FSANZ NPSC. These levels were then compared to the mean levels of nutrients for foods that fail the FSANZ NPSC (regardless if they carry a health-related claim).

Results

A more in-depth description of the database is given in Chapter 4, a brief summary of the results relevant to this chapter is given here. In total, 2034 foods were sampled with each of the five countries contributing 20% of the database. The largest food group in the database was Foods high in fat and/or sugar which comprised 36% (95% CI 34%, 38%) of the sample. Dairy and alternatives and Fruit and vegetables each comprised 8% (95% CI 7%, 9%) of the database (Table 5.1).

Table 5.1 Description of database (n, %, 95% confidence intervals)

Eatwell Guide group	**Number of foods**	**Health claims**	**Nutrition claims**	**Any claim**
Potatoes, bread, rice, pasta or other starchy carbohydrates	194, 10% (8%, 11%)	23, 12% (7%, 16%)	53, 27% (21%, 34%)	57, 29% (23%, 36%)
Dairy or dairy alternatives	162, 8% (7%, 9%)	34, 21% (15%, 27%)	64, 40% (32%, 47%)	75, 46% (39%, 54%)
Foods high in fat and/or sugar	740, 36% (34%, 38%)	66, 9% (7%, 11%)	152, 21% (18%, 24%)	172, 23% (20%, 26%)
Beans, pulses, fish, eggs, meat and other protein.	300, 15% (13%, 16%)	24, 8% (5%, 11%)	46, 15% (11%, 19%)	53, 18% (13%, 22%)
Fruit and vegetables	159, 8% (7%, 9%)	16, 10% (5%, 15%)	46, 29% (22%, 36%)	53, 33% (26%, 41%)
Miscellaneous foods	279, 14% (12%, 15%)	53, 19% (14%, 24%)	62, 22% (17%, 27%)	86, 31% (25%, 36%)
Composite foods	200, 10% (9%, 11%)	6, 3% (1%, 5%)	28, 14% (9%, 19%)	32, 16% (11%, 21%)
Total	**2034, 100%**	**222, 11% (10%, 12%)**	**451, 22% (20%, 24%)**	**528, 26% (24%, 28%)**

Overall, 26% (95% CI 20%, 24%) of foods carried a health-related claim, 22% (95% CI 20%, 24%) of foods carried a nutrition claim, and 11% carried a health claim (95% CI 10%, 12%). The prevalence of claims varied by food group and by whether the type of claim was a health claim or a nutrition claim. Dairy and alternatives had the largest proportion of products carrying a health claim (21%, 95% CI 15%, 27%) and nutrition claim (40%, 95% CI 32%, 47%), and Composite foods had the lowest proportion of foods carrying a health claim (3%, 95% CI 1%, 5%) and nutrition claims (14%, 95% CI 9%, 19%).

Table 5.2 Missing nutritional data

	Germany	Netherlands	Spain	Slovenia	UK	Total
Number of foods	399	416	405	416	398	2034
Missing data (n, %) Nutrients						
Energy	55 (14%)	41 (10%)	62 (15%)	128 (31%)	32 (8%)	318 (16%)
Protein	55 (14%)	44 (11%)	61 (15%)	129 (31%)	34 (9%)	32 (16%)
Carbohydrate	55 (14%)	43 (10%)	61 (15%)	129 (31%)	33 (8%)	321 (16%)
Total sugars	109 (27%)	80 (19%)	125 (31%)	196 (47%)	43 (11%)	553 (27%)
Fat	55 (14%)	42 (10%)	61 (15%)	131 (32%)	33 (8%)	322 (16%)
Saturated fat	110 (28%)	79 (19%)	123 (30%)	193 (46%)	43 (11%)	548 (26%)
Fibre	123 (31%)	103 (25%)	161 (40%)	217 (52%)	49 (12%)	653 (32%)
Sodium	111 (28%)	82 (20%)	126 (31%)	208 (50%)	42 (11%)	569 (28%)
Foods without any nutritional information	54 (14%)	41 (10%)	57 (14%)	128 (31%)	31 (8%)	311 (15%)
Foods with nutritional information for the 'Big 8' nutrients	273 (69%)	306 (74%)	234 (58%)	194 (47%)	348 (87%)	1355 (67%)
Missing nutritional data points	**21%**	**24%**	**15%**	**40%**	**10%**	**22%**

Note: 'Big 8' nutrients refers to the following nutrients: energy, protein, carbohydrates, and total fat (the 'big 4'), plus total sugars, saturated fat, fibre, and sodium.

In total, 22% of the nutritional data were missing (i.e. not present on the food label), this ranged from 10% of data from the UK to 40% of data from Slovenia. The provision of nutrition labelling varied by country and by nutrient. The UK had the strongest presence of nutrition labelling in comparison to the other four countries, only 8% of the foods sampled did not carry any nutritional information, whereas in Slovenia 31% of products did not contain any nutritional information.

With regard to the 'Big 4' nutrients (energy, protein, carbohydrates, and total fat) the

provision of data was similar within countries but varied between countries, for example in the UK 8% of foods did not have information for one of the big 4 nutrients. With regard to the remaining nutrients (total sugars, saturated fat, fibre, and sodium) there was greater variation both within countries and between countries: 13% of foods in the UK did not have this information whereas 53% of foods in Slovenia did not have this information. In all counties, fibre was the nutrient with the most missing data.

Table 5.3: Mean level of nutrients by food category (Kruskal Wallis test) and claim type (Mann-Whitney test)

Eatwell Guide food group	**Energy (KJ/100g)**	**Energy (Kcal/100g)**	**Protein (g/100g)**	**Carbohydrate (g/100g)**	**Total sugars (g/100g)**	**Total fat (g/100g)**	**Saturated fat (g/100g)**	**Fibre (g/100g)**	**Sodium (mg/100g)**
Potatoes, bread, rice, pasta or other starchy carbohydrates	1418.5	339.0.	9.1	60.4	8.4	5.6	1.9	5.2	267.3
Dairy or dairy alternatives	699.7	167.2	9.3	7.5	6.7	10.7	6.0	0.2	273.9
Foods high in fat and/or sugar	1342.8	320.9	3.6	40.3	24.1	16.2	6.3	1.7	262.5
Beans, pulses, fish, eggs, meat and other protein	1022.3	244.3	16.6	6.9	1.5	16.3	4.6	1.9	809.7
Fruit and vegetables	330.4	79.0.	1.8	11.3	8.9	2.9	0.6	2.3	201.5
Miscellaneous foods	545.1	130.7	3.8	19.5	11.1	3.5	1.5	2.2	2700.7
Composite foods	713.2	170.5	7.7	16.7	4.0	7.8	2.8	1.5	1021.2
P value	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
Mean levels of nutrients by claim type									
Without health claims	1051.4	251.4	7.0	28.2	13.7	12.0	4.7	1.9	707.7
With health claims	851.9	203.6	5.5	25.5	10.1	8.7	2.2	2.7	161.1
P value	0.00	0.00	0.00	0.03	0.02	0.00	0.00	0.68	0.00
Without nutrition claims	1078.9	257.8	7.1	27.7	14.1	12.9	5.1	1.8	689.2
With nutrition claims	877.9	210.1	6.1	28.2	10.9	8.0	2.4	2.7	503.6
P value	0.00	0.00	0.00	0.98	0.84	0.00	0.00	0.07	0.00
No health-related claims	1100.7	263.1	7.3	28.2	14.3	13.1	5.3	1.8	715.3
At least one health-related claim	850.0	203.4	5.8	26.9	10.8	7.9	2.3	2.5	469.3
P value	**0.00**	**0.00**	**0.00**	**0.12**	**0.22**	**0.00**	**0.00**	**0.66**	**0.00**

Table 5.3 shows the mean levels of nutrients by claim type and by food category – these analyses, along with Table 5.4 and 5.5, uses food label data only (i.e. does not include any data from the UK Nutrient Databank).

The mean levels of nutrients differed by food group. Fruit and vegetables had the lowest average amounts of energy (79kcal/100g) and total fat (2.9g/100g), saturated fat (0.6g/100g), and sodium (202mg/100g). Foods high in fat and/or sugar had high (although not the highest) levels of energy (321kcal/100g), and fat (16.2g/100g) and the highest amount of sugar (24g/100g).

Potatoes, bread, rice, pasta or other starchy carbohydrates had the highest amounts of energy (339kcal/100g) and fibre (5.2g/100g). Dairy and alternatives had the highest average levels of saturated fat (6g/100g) and the lowest levels of fibre (0.2g/100g). Beans, pulses, fish, eggs, meat and other protein had the highest levels of protein (17g/100g), total fat (16.3g/100g), and the lowest levels of sugar (2g/100g). Miscellaneous foods had the highest levels of sodium (2701mg/100g). In the previous chapter, I showed that the prevalence of health-related claims also varied by food category, therefore food category is a potential confounder of the association between health-related claims and nutritional quality.

Table 5.3 also shows the mean levels of nutrients of foods with and without health claims, nutrition claims or either health or nutrition claims. These results are not adjusted for food group. Foods carrying claims had statistically significant lower levels of energy, protein, total fats, saturated fats, and sodium. Foods carrying health claims had statistically significant lower levels of total sugars whereas foods carrying nutrition also had lower levels of sugars but this difference was not statistically significant. Foods carrying claims had higher levels of fibre but this difference was not significant for any claim types.

The average levels of protein, carbohydrate, and fibre were similar across the models. The average energy content for foods carrying health claims was 204 kcal/100g, this was lower

than for foods not carrying health claims (251kcal/100g) and also lower for the average for foods carrying nutrition claims (210kcal/100g).

Foods that carried claims had 3-4g/100g less sugar than foods that did not carry claims. The largest differences were seen with regards to the total fat levels. Foods carrying at least one health-related claim had, on average, 8g/100g of total fat, whereas foods that did not carry a claim had 13g/100g. The differences were slightly smaller for foods carrying health claims (2g less per 100g) than for foods carrying nutrition claims (5g less per 100g).

There was greater variance in the average amount of sodium. Whilst foods carrying claims had lower levels of sodium than foods not carrying claims, foods carrying nutrition claims had much higher sodium levels (504mg/100g) than foods carrying health claims had (161mg/100g).

Tables 5.4 and 5.5 shows the regression analyses for the differences in the mean levels of nutrients for foods that carry health-related claims and foods that do not. Model 2 adjusts for food group whereas Model 1 does not include any adjustments and is provided purely for comparison with the non-parametric results displayed in Table 5.3. The differences produced by the regression analyses of the mean levels of nutrients (Table 5.4 and 5.5) are very similar to the non-parametric test results (Table 5.3), although for several nutrients results which were statistically significant in the non-parametric tests lose statistical significance, and also some differences gain statistical significance.

The results that adjust for food group (Model 2, Table 5.4) show that foods carrying health claims have statistically significant lower levels of energy (-29.3kcal/100g), protein (-1.2g/100g), total sugars (-3.1/100g), saturated fat (-2.4/100g), sodium (-842.4mg/100g), and more fibre (+0.8g/100g). There are also lower levels of sugar (-0.7g/100g) and total fat (-2.1/100g) but these differences are not statically significant.

Table 5.4 Adjusting for food category, differences in the mean level of nutrients between foods that carry health claims and foods that do not, and foods that carry health claims AND pass the NPSC and those that do not

	Health claims						Health claims – only those that pass NPSC					
	Model 1	**P**	**CI**	**Model 2***	**P**	**CI**	**Model 1**	**P**	**CI**	**Model 2***	**P**	**CI**
Energy (KJ/100g)	-199.5	0.00	(-312.9, -86.8)	-121.9	0.02	(-224.5, -19.4)	-370.1	0.00	(-500.0, -241.6)	-233.8	0.00	(-351.0, -116.7)
Energy (Kcal/100g)	-47.8	0.00	(-74.9, -20.7)	-29.3	0.01	(-53.8, -4.8)	-88.8	0.00	(-119.6, -57.9)	-56.0	0.00	(-84.0, -28)
Protein (g/100g)	-1.5	0.01	(-2.6,-0.4)	-1.2	0.01	(-2.1, -0.4)	-1.9	0.00	(-3.1, -0.6)	-1.6	0.00	(-2.6, -0.6)
Carbohydrate (g/100g)	-2.7	0.20	(-6.8, 1.4)	-0.7	0.67	(-4.0, 2.5)	-9.8	0.00	(-14.4, -5.1)	-6.7	0.00	(-9.9, -2.5)
Total sugars (g/100g)	-3.5	0.02	(-6.4, -0.7)	-3.1	0.02	(-5.6, -0.5)	-8.4	0.00	(-11.6, -5.2)	-7.3	0.00	(-10.2, -4.4)
Total fat (g/100g)	-3.3	0.01	(-5.7, 1.0)	-2.1	0.06	(-4.4, 0.1)	-4.6	0.00	(-7.2, -1.9)	-2.5	0.06	(-5.1, -0.1)
Saturated fat (g/100g)	-2.5	0.00	(-3.5, -1.6)	-2.4	0.00	(-3.3, -1.4)	-3.3	0.00	(-4.4, -2.3)	-2.9	0.00	(-3.9, -1.8)
Fibre (g/100g)	0.7	0.01	(0.2, 1.3)	0.8	0.00	(0.3, 1.3)	0.9	0.00	(0.4, 1.5)	1.0	0.00	(0.5, 1.6)
Sodium (mg/100g)	-546.7	0.03	(-1052, -40)	-842.4	0.00	(-1348.4, -336.5)	-594.3	0.04	(-1166.1, -29.8)	-877.6	0.00	(-1443.2, -312.0)

*Model 2 is adjusted for food group, Model 1 is not.

Table 5.5 Adjusting for food category, differences in the mean level of nutrients between foods that carry nutrition claims and foods that do not, and foods that carry at least one health or nutrition claim, and foods that do not carry any claims

	Nutrition claims						Any claim					
	Model 1	**P**	**CI**	**Model 2***	**P**	**CI**	**Model 1**	**P**	**CI**	**Model 2***	**P**	**CI**
Energy (KJ/100g)	-201.0	0.00	(-285.0, -117.0)	-149.9	0.00	(-225.5, -74.3)	-250.7	0.00	(-339.9,-170.6)	-183.1	0.00	(-255.9, -110.4)
Energy (Kcal/100g)	-47.7	0.00	(-67.8, -27.6)	-35.7	0.00	(-53.8, -17.6)	-59.6	0.00	(-78.8, -40.5)	-43.7	0.00	(-61.1, -26.3)
Protein (g/100g)	-1.1	0.01	(-1.9, -0.26)	-0.6	0.05	(-1.2, 0.0)	-1.5	0.00	(-2.3, -0.7)	-1.0	0.00	(-1.6, -0.4)
Carbohydrate (g/100g)	0.5	0.76	(-2.6, 3.5)	0.9	0.48	(-1.5, 3.3)	-1.3	0.37	(-4.3, 1.6)	-0.1	0.92	(-2.5, 2.2)
Total sugars (g/100g)	-3.2	0.00	(-5.4, -1.1)	-3.0	0.00	(-4.9, -1.1)	-3.5	0.00	(-5.5, -1.4)	-3.2	0.00	(-5.0, -1.3)
Total fat (g/100g)	-4.9	0.00	(-6.6, -3.1)	-3.8	0.00	(-5.5, -2.2)	-5.2	0.00	(-6.9, -3.6)	-4.1	0.00	(-5.7, -2.5)
Saturated fat (g/100g)	-2.7	0.00	(-3.5, -2.0)	-2.6	0.00	(-3.3, -1.9)	-3.0	0.00	(-3.7, -2.4)	-2.9	0.00	(-3.6, -2.2)
Fibre (g/100g)	0.9	0.00	(0.5, -1.3)	0.9	0.00	(0.5, 1.3)	0.7	0.00	(0.3, 1.1)	0.7	0.00	(0.3, 1.1)
Sodium (mg/100g)	-185.6	0.34	(-564.0,192.8)	-243.3	0.21	(-620.9,134.4)	-246.0	0.19	(-610.8,118.9)	-354.7	0.06	(-721.3, 11.9)

*Model 2 is adjusted for food group, Model 1 is not.

The second section of Table 5.4 shows the difference in the average levels of nutrients for foods that carry health claims and pass the FSANZ NPSC compared to foods that do not pass the FSANZ NPSC (i.e. regardless of whether they carry a health-related claim). Restricting the prevalence of health claims in this manner increases the differences between foods that carry health claims and foods that do not. Foods carrying claims have statistically significant lower levels of energy (-56kcal 100g), protein (-1.6g/100g), carbohydrates (-6.7g/100g), total sugars (-7g/100g), total fat (-2.5g/100g), saturated fat (-2.9g/100g), and sodium (-878mg/100g), and significantly more fibre (1.0g/100g).

Table 5.5 shows the regression analyses for the difference in the mean levels of nutrients for foods that carry nutrition claims and for foods that do not. The unadjusted model (model 1) results are again very similar to the non-parametric analyses and only differ with regards to the significance of the fibre levels which were not statistically significant in Table 5.3 but are in the parametric tests, and sodium which were statistically significant in in the non-parametric tests but are not in the parametric tests.

After taking food group into account (model 2) foods that carry nutrition claims have, on average, per 100g, significantly; less energy (-35.7kcal), protein (-0.6g), total sugars (-3.0g), total fat (-3.8g), saturated fat (-2.6g), and more fibre (+0.9g). Foods carrying nutrition claims, had more carbohydrate (+0.9g) and less sodium (-243.3mg) but these results were not statistically significant.

The second section of Table 5.5 shows the results of the regression analyses for the differences in the mean levels of nutrients for foods that carry at least one health-related claim compared to foods that do not carry any health-related claims. These results follow a similar pattern as that found for nutrition claims; foods carrying at least one health-related claim have, on average, per 100g, significantly; less energy (-43.7kcal), protein (-1.0g), total sugars (-3.2g), total fat (-4.1g), saturated fat (-2.9g), and more fibre (+0.7g). The differences for carbohydrates (-0.1g) and sodium (-354.7mg) were not statistically significant.

Table 5.6 Food Standards Australia New Zealand Nutrient Profiling Scoring Criterion (FSANZ NPSC), (n, %, 95 CI)

Country	**Foods that pass the FSANZ NPSC**	**Foods that do not carry any claims that pass the FSANZ NPSC**	**Foods that carry health claims that pass the FSANZ NPSC**	**Foods that carry nutrition claims that pass the FSANZ NPSC**
Germany	169, 42% (37%, 47%)	124, 39%, (34%, 45%)	26, 68% (53%, 84%)	38, 54% (42%, 66%)
Netherlands	161, 40% (35%, 44%)	95, 31% (26%, 36%)	48, 81% (71%, 92%)	40, 55% (43%, 66%)
Spain	182, 45% (40%, 50%)	115, 38% (32%, 43%)	20, 67% (49%, 85%)	61, 66% (56%, 75%)
Slovenia	161, 39% (34%, 44%)	113, 36% (31%, 42%)	26, 51% (37%, 65%)	39, 50% (39%, 61%)
UK	190, 48% (43%, 53%)	90, 35% (29%, 41%)	36, 80% (67%, 92%)	98, 73% (65%, 80%)
Total	863, 43% (41%, 45%)	537, 36% (34%, 38%)	156, 70% (64%, 76%)	276, 61% (57%, 66%)
P value	**0.047**	**0.309**	**0.005**	**0.005**

Table 5.6 shows the proportion of foods that pass the FSANZ NPSC. Overall, 43% (95% CI 41%, 45%) of all foods sampled passed the FSANZ NPSC. Fewer foods sampled from the Netherlands (40%, 95% CI 35%-44%) and Slovenia (39%, 95% CI 34%, 44%) passed the FSANZ NPSC. A chi-squared test was conducted to test whether the proportion of claims that pass the FSANZ NPSC significantly differed between countries, this was significant (Pearson chi^2 =9.6, 4df, $p < 0.05$)

Foods that carry health claims are more likely to pass the FSANZ NPSC (70%, 95% CI 64%, 76%), than foods carrying nutrition claims (61%, 95% CI 57%, 66%), or foods carrying no claims (36%, 95% CI 34%, 38%). A logistic regression was conducted to estimate the odds of passing the FSANZ NPSC when a health-related claim was present, foods carrying health claims were 3.6 times (OR 3.6, 95% CI 2.6, 4.8), and foods carrying nutrition claims were 2.7 times (OR 2.7, 95% CI 2.1, 3.3) more likely to pass the FSANZ NPSC than foods that did not carry a health/nutrition claim.

In Slovenia, 51% (95% CI 37%, 65%) of foods carrying health claims passed the FSANZ NPSC, whereas in the Netherlands and the UK, 80% (95% CI 67%, 92%) and 81% (95% CI 71%, 92%), of foods carrying health claims passed the model, the differences between countries were statistically significant (Pearson chi^2 =14.7, 4df, $p < 0.005$). With regard to foods carrying nutrition claims, the UK had the highest proportion of foods that passed the model (73%, 95% CI 65%, 80%). compared to the other countries. The country differences were statistically significant (Pearson chi^2 =15.0, 4df, $p < 0.005$).

Table 5.7 shows the correlations between the nutritional data recorded from the food label and those taken from the UK Nutrient Databank. The strength of the correlation was measured using Pearson's r correlation coefficient [151] where -1 indicates a perfect negative relationship, +1 a perfect positive linear correlation, and 0 equals no linear correlation. Evans (1996) [152] suggested the following thresholds to define the strength of the r correlation: 0.00-0.19 = "very weak", 0.20-0.39 = "weak", 0.40-0.59 = "moderate", 0.60-0.79 = "strong", 0.80-1.0= "very strong". Overall, the nutritional data recorded from the food label is well-correlated to the matched products in the UK Nutrient Databank. Using Evan's proposed thresholds, 35 of the possible 40 correlations, would be categorised as 'strong' or 'very strong'.

Table 5.7 Correlations (Pearson's r) between nutritional information recorded from food labels and the matched food in the UK Nutrient Databank, by country

	Germany		**Netherlands**		**Spain**		**Slovenia**		**UK**		**All**	
	n	**r**	**n**	**r**	**n**	**r**	**n**	**r**	**n**	**r**	**n**	**r**
Energy (kj)	344	0.95 (0.01)	359	0.91 (0.01)	343	0.90 (0.01)	279	0.93 (0.01)	366	0.95 (0.01)	1691	0.93 (0.00)
Energy (kcal)	344	0.95 (0.01)	358	0.90 (0.01)	343	0.90 (0.01)	279	0.92 (0.01)	366	0.94 (0.01)	1690	0.92 (0.00)
Protein	344	0.93 (0.01)	355	0.79 (0.02)	344	0.77 (0.02)	278	0.87 (0.01)	364	0.91 (0.01)	1685	0.85 (0.01)
Carbohydrate	344	0.94 (0.01)	357	0.89 (0.01)	344	0.87 (0.01)	278	0.87 (0.01)	365	0.94 (0.01)	1688	0.90 (0.00)
Total sugars	290	0.92 (0.01)	322	0.67 (0.03)	280	0.77 (0.03)	211	0.75 (0.03)	355	0.83 (0.02)	1458	0.80 (0.01)
Fat	344	0.93 (0.01)	357	0.87 (0.01)	344	0.87 (0.01)	276	0.96 (0.01)	365	0.92 (0.01)	1686	0.91 (0.00)
Saturated fat	289	0.86 (0.02)	322	0.84 (0.02)	282	0.65 (0.03)	214	0.83 (0.01)	355	0.87 (0.01)	1462	0.82 (0.01)
Fibre (Englyst [153])	276	0.58 (0.03)	299	0.58 (0.04)	244	0.26 (0.06)	190	0.72 (0.03)	349	0.75 (0.02)	1358	0.55 (0.02)
Fibre (Southgate [154])	276	0.72 (0.05)	299	0.47 (0.05)	244	0.17 (0.06)	190	0.48 (0.06)	348	0.70 (0.03)	1358	0.41 (0.02)
Sodium	288	0.50 (0.04)	320	0.79 (0.02)	279	0.20 (0.06)	199	0.39 (0.06)	356	0.66 (0.03)	1442	0.67 (0.01)

The strength of the fibre correlations are lower than for the other nutrients. The UK Nutrient Databank contains two fibre estimates; the Englyst estimate [153] and the Southgate estimate [154]. The Englyst method measures the amount of starch polysaccharide (NSP) present in the food. NSP consists of insoluble fibre which cannot be broken down by the body therefore passes through the digestion system more quickly, and soluble fibre which slows digestion by attracting water and then turning into a gel. Southgate fibre also measures soluble and insoluble fibre but also includes fibre from plant cell walls and other substances and therefore usually gives higher measures than the Englyst /NSP estimate. Overall, the Englyst method is better correlated (r = 0.55) than the Southgate fibre (r =0.41) therefore this data has been used to supplement the missing nutritional data.

The strength of the correlation between the sodium data recorded from the food label and of the matched products in the UK Nutrient Databank is also lower than for most other nutrients. For all of the countries the r score is 0.67 (i.e. “strong”), however there is some country variation. In Spain there is a “very weak” correlation between the food label sodium levels and the UK Nutrient Databank sodium levels, whereas in Germany and the Netherlands there is an r of 0.79 indicating a “strong” correlation. The sodium levels recorded from the Slovenian food labels has an r of 0.39 (“weak”) and the UK data has an r of 0.66 (“strong”).

Table 5.8 Correlations (Pearson's r) between nutritional information recorded from; Slovenian food labels, the Slovenian Open Platform for Clinical Nutrition database ('OPEN DB'), and the UK Nutrient Databank.

Nutrient	Food label - OPEN DB		Food label - UK Nutrient Databank		UK Nutrient Databank - OPEN DB	
	n	r	n	r	n	r
Energy (kj)	287	0.92	279	0.93	403	0.93
Energy (kcal)	287	0.92	279	0.92	403	0.93
Protein	263	0.87	278	0.87	352	0.86
Carbohydrate	274	0.86	278	0.87	369	0.87
Total sugars	171	0.80	211	0.75	286	0.85
Total fat	256	0.95	276	0.96	346	0.91
Saturated fat	186	0.84	214	0.83	338	0.76
Fibre	155	0.81	190	0.48	284	0.61
Sodium	185	0.38	199	0.39	365	0.80

Table 5.8 displays the Pearson's correlation coefficients for the nutritional data recorded from the Slovenian food labels and a Slovenian food composition database (Open DB) and the UK Nutrient Databank. Overall, using a country-specific food composition table does not greatly improve the strength of the correlations between nutritional data recorded from the food label and the corresponding nutritional data from the matched data in the food composition table. For total sugars, saturated fat, and fibre, the correlations between the food label data and the OPEN DB are higher than the equivalent correlations for when the foods were matched to the UK Nutrient Databank. For total sugars and saturated fat the improvement is quite small, r=0.83 to r=0.84 for saturated fat, and r=0.75 to r=0.80 for total sugars. However,

the improvement is greater for fibre (*r*=0.48 for Southgate fibre to *r*=0.81). The strength of the correlation remains unchanged for Energy (kcal) (r=0.92) and protein (r=0.87). For the remaining nutrients (carbohydrates, total fat, and sodium) the correlation is slightly weaker - the r score is reduced by 0.01 when matched to the OPEN DB compared to matching to the UK Nutrient Databank. Sodium remains weakly correlated: r= 0.38 when matched to OPEN DB and r = 0.39 when matched to the UK Nutrient Databank.

Table 5.9 FSANZ NPSC agreement when using different data sources to supplement missing food label data for Slovenian products (n, %, 95% CI)

Supplementary data source	**Foods that pass the NPSC**	**Foods that do not carry any claims that pass the NPSC**	**Foods that carry health claims that pass the NPSC**	**Foods that carry nutrition claims that pass the NPSC**
UK Nutrient Databank (n= 413)	161, 39% (34%, 44%)	113, 36% (31%, 42%)	26, 51% (37%, 65%)	39, 50% (39%, 61%)
OPEN database (n= 312)	144, 46% (41%, 52%)	98, 42% (35%, 48%)	25, 76% (60%, 91%)	38, 61% (49%, 74%)
Agreement: n, % agreement, Kappa (standard error)	**296, 95%, 0.90 (0.06)**	**221, 94%, 0.88 (0.07)**	**32, 97%, 0.92 (0.17)**	**61, 98%, 0.97 (0.13)**

When matching to the UK Nutrient Databank a suitable equivalent could not be found for 2 products, when matching to the OPEN DB there were ten products for which a suitable alternative could not be identified. In order to apply the FSANZ NPSC data on the following nutrients are required; energy, protein, carbohydrates, total sugars, fat, saturated fat, fibre, sodium and calcium.

Table 5.9 shows the results of the FSANZ NPSC model for when the missing food label data were supplemented with either the UK Nutrient Databank or the OPEN DB. Using the OPEN DB to supplement the missing data allowed 312 foods to be assessed using the FSANZ NPSC, whereas using the UK Nutrient Databank allowed 413 foods to be assessed.

A higher proportion of foods pass the FSANZ NPSC when foods are matched to the OPEN DB (46%, 95% CI 41%, 52%) than when they are matched to the UK Nutrient Databank (39%, 95% CI 34%, 44%). A similar pattern was seen when observing only foods that do not carry any health-related claims, when supplemented with the UK Nutrient Databank 36% (95% CI 31%, 42%) of foods passed the NPSC and 42% (95% CI 35%, 48%) passed the model when supplemented with the OPEN DB.

Larger differences were seen in regards to foods that carry health claims and nutrition claims – 76% (95% CI 60%, 91%) of foods carrying health claims and 61% (95% CI 49%, 74%) of foods carrying nutrition claims passed the FSANZ NPSC when data were supplemented with the OPEN DB and 51% (95% CI 37%, 65%) of foods carrying health claims and 50% (95% CI 39%, 61%) of foods carrying nutrition claims passed the FSANZ NPSC when they were supplemented with the UK Nutrient Databank.

There was a high percentage agreement between the FSANZ classifications when the OPEN DB was used to supplement data compared to when the UK Nutrient Databank was used. For all foods the percentage agreement was 95%, it was slightly lower for foods that don't carry any claims (94%), but higher for foods that carry health claims (97%) and for foods that carry nutrition claims (98%). The Cohen kappa scores were also very high (95% CI 0.88, 0.97), using Viera and Garrett's [155] suggested thresholds for the interpretation of kappa, these scores represent an "Almost perfect agreement".

Discussion

Main findings

Foods carrying at least one health-related claim have, on average, significantly lower levels of: energy (-43.7kcal/100g), protein (1.0g/100g), total sugars (-3.2g/100g), total fat (-4.1g/100g), and saturated fat (-2.9g/100g), and significant higher levels of fibre (+0.7g/100g).

Foods that carry health claims are more likely to pass the FSANZ NPSC (70%, 95% CI 64%, 76%), than foods carrying nutrition claims (61%, 95% CI 57%, 66%), or foods carrying no claims (36%, 95% CI 34%, 38%). Restricting health-related claims to foods that pass the FSANZ NPSC improves the nutritional quality of foods carrying health claims. In this scenario, foods carrying claims have significantly lower levels of energy (-56.0kcal/100g), protein (-1.6g/100g), carbohydrates (-6.7g/100g), total sugars (-7.3g/100g), saturated fat (-2.9g/100g), and sodium (-877.6mg/100g), and significantly higher levels of fibre (+1.0g/100g).

Comparison to other literature

Comparisons to previous literature are difficult due to varying definitions, categorisations, and sampling methods used in previous studies. Furthermore, to the best of my knowledge, there have been no other studies that compare the nutritional compositions of foods carrying health-related claims compared to foods that do not, using a representative sample of foods from multiple countries using a sampling frame where most foods/food categories were eligible for inclusion.

The results here are similar to the results of a previous study conducted on a random sample of foods sampled from a food retailer's website [136], in that overall, it appears that health-related claims have a nutritionally more favourable composition than foods that do not carry health-related claims. However, in that study I did not find any significant differences in the

levels of total sugars or sodium. That study also randomly sampled foods across most food categories however, it only included products from a single retailer and store type (a national supermarket) and therefore may not be representative of all pre-packaged foods available to purchase in the UK.

The results presented in this chapter differ to that of the Brazilian survey of foods carrying nutrition claims [144], which found that foods carrying nutrition claims often had a worse nutritional composition than foods not carrying claims. However, that study included all products available to purchase in a large supermarket that were defined as targeted to children (n=535) – (e.g. one criterion was that cartoon characters on the food label) and did not also consider health claims.

Within the UK, a study of store-brand product ranges for four different types of ready meals found that 'healthy' ranges had lower median levels of energy, fat, saturated fat, and salt, but higher levels of carbohydrates and total sugars than the equivalent 'standard' and 'value' ranges [145]. However, this study was concerned with product ranges/brands rather than individual products. Therefore products in the 'standard' and 'value' ranges may have also carried health-related claims.

Other studies have focussed on particular types of claims. For example, an Australian study examined all fruit snacks, soups, and fruit and vegetable juices and drinks available to purchase in five supermarkets [142]. This study found that 48% of products carried a fruit and vegetable content claim and these products had higher energy, total sugars, saturated fat, sodium and less fibre than the equivalent amount (as referenced in the claim) of fruits and/or vegetables. However, this study did not compare with foods that did not carry such claims, but instead to the equivalent amount of fruit and vegetables referenced in the claim. The study also found that 34% of foods carrying fruit and vegetable claims failed the FSANZ NPSC which is similar to the results presented in this chapter where 39% of foods carrying nutrition claims

and 30% of foods carrying health claims failed the FSANZ NPSC. Similarly, in our earlier study where foods were sampled from a food retailer's website [136] I found that 38% of foods carrying health claims and 34% of foods carrying nutrition claims failed the FSANZ NPSC.

A study in the USA used an existing marketing database, Mintel's Global New Product Database (GPND), to examine 1189 breakfast cereals and 1032 ready meals released in the US between 2006 and 2010. The study found that presence of a health-related claim was not a good predictor for passing the US FDA nutrient profile model for the definition of 'healthy'. The same study also examined the relationship between the presence of a health-related claim and whether a food had high, medium, or low levels of nutrients (in relation to foods in the high, medium, or low tertiles for each nutrient). That study found that breakfast cereals carrying health-related claims were 27% more likely to have low levels of sodium (relative to foods with high levels of sodium). Health claims were 3.6 (for 'healthy/other claims') and 4.3 (for 'health/implied claims') times more likely to have a high fibre content (than foods in the lowest tertile for fibre content), but those carrying negative nutrient claims were 44% less likely to have a high fibre content. Ready meals carrying positive nutrient claims were 3 times less likely to be low in fat (relative to high) and products carrying claims were less likely to have a high sodium content (no pattern was observed with regards to sugar content).

Strengths and Limitations

As this analysis used the same database as was described in Chapters 3 and 4, the same limitations apply. For example, two different methods of sampling were used, one using a list of products and one which involved making a floor plan of the store (Chapter 3, p77).

A limitation of this database is that, out of intended number of data points (i.e. 8 nutrients * 2034 products = 16272 data points), 22% of the data were missing from the final database. The proportion of missing data varied between countries, from 9.7% of missing data points in

the UK to 40% missing data points from the Slovenian products. There was also variation within countries, for example in Slovenia, 52% of products did not provide the amount of fibre.

This also made it necessary to supplement the data in order to apply the FSANZ NPSC. Due to time and budget constraints the UK Nutrient Databank was used to supplement missing data from each country. The supplemented data were well correlated with the food label data for most nutrients but weaker correlations were seen for fibre and sodium. Where there was no nutrient data provided on the food label (15% of sampled foods), it is not possible to determine how appropriate the matched product is to the sampled product. The use of a non-country specific nutrient databank may be a potential weakness of the study, however the validity exercise conducted with the Slovenian foods indicated only minor improvements in the strength of the correlation between the label data and the matched data when country-specific food composition tables were used.

Another limitation of this study is the use of parametric tests on non-normally distributed data. However, as food category was shown to be a potential confounder it was necessary to use analyses that allow adjusted models. The results from the unadjusted parametric tests, generally, followed a similar pattern to the non-parametric tests therefore I believe the use of these tests were justified.

Due to the multiple comparisons of mean values it may be considered appropriate to use Bonferroni adjustments to reduce the likelihood on incorrectly rejecting the null hypothesis. (Type I errors). However, as these are exploratory analyses and have limited statistical power, adjusting for multiple comparisons may increase the chances of falsely accepting the null hypotheses (Type II errors).

In Tables 4.3 and 4.4, there are country differences both in the types of food sampled and in the health-related claim prevalence. Therefore, it would have been ideal to adjust for country

(in addition to food group) in the adjusted regression analyses. However, as this sample already has limited statistical power it was important to limit what factors to adjust for.

Implications

Whilst the nutritional differences between foods that carry health-related claims and foods that do not may appear modest, previous modelling studies have shown that even small dietary changes can have a significant effect when they are scaled-up to a population level. Therefore, in Chapter 7, I model the effect of these nutritional differences on mortality rates in the UK.

The findings of this study may be of interest to the European Commission's evaluation of Regulation (EC) 1924/2006. Whilst foods carrying claims, on average, have a slightly better nutritional composition than foods that do not carry claims, 30% of foods carrying health claims and 39% of foods carrying nutrition claims do not pass the FSANZ NPSC, meaning these claims would be illegal in Australia and New Zealand.

Restricting health-related claims using the FSANZ NPSC would increase the nutritional differences between foods carrying health-related claims and foods that do not. However, the restriction of claims on foods when they are, on average, nutritionally superior to foods without claims, may have a negative impact on the diet. This will be discussed further in Chapter 7.

Summary

Foods that carry health-related claims have a slightly better nutritional composition than foods that do not. The EC is currently evaluating whether a nutrient profile model is required to regulate claims so that only foods that meet a minimum nutritional criteria may carry claims.

This chapter shows that using the FSANZ NPSC would improve the average nutritional composition of foods carrying claims but would impact some nutrients more than others. In the next chapter I assess whether the choice of which nutrient profile is important. I model the impact of applying the three nutrient profile models on the average nutrient levels, and whether the models agree on which foods ('agreement') and how many foods should carry claims ('strictness') should be able to carry health-related claims.

6. Nutrient profile models used for the regulation of health-related claims

Introduction

In the previous chapter I compared the mean levels of energy, protein, carbohydrates, total sugars, saturated fat, total fat, fibre, and sodium for foods that carry health-related claims and foods that do not. The findings were that foods that carried health-related claims had significantly lower levels of: energy, protein, total sugars, total fat, and saturated fat, and significantly higher levels of fibre. I also showed that using a nutrient profile model, such as the Food Standards Australia New Zealand's Nutrient Profiling Scoring Criterion (FSANZ NPSC, [47]), to restrict health-related claims would further improve the nutritional quality of foods carrying claims.

In this chapter I assess whether different nutrient profile models, designed for the same purpose, produce similar results in terms of the proportion of foods the model 'passes' (i.e. the strictness of the model) and whether they categorise foods the same way (i.e. the agreement between models).

Background

Nutrient profiling is "the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health" [44]. The algorithms behind these classifications or rankings are called nutrient profile models. Most nutrient profile models provide an overall evaluation of a food's nutritional composition as opposed to evaluating the levels of single nutrients in isolation. Nutrient profiling has numerous applications, for example, helping consumers identify 'healthier' foods, e.g. through

supporting health logo schemes, and identifying 'less healthy' foods e.g. for the regulation of TV advertising of foods to children [45].

Nutrient profile models can be category specific or 'across-the-board'. In category-specific models there are separate nutrient thresholds or scorings for foods in different food categories, for example, the nutrient profile model used in the previous chapter, the FSANZ NPSC [47], has three food categories; drinks, cheeses, spreads and oils, and other foods. Conversely, 'across-the-board' models the same scoring is applied to all foods. A previous study suggested that category-specific models were better suited to identify healthier foods [156].

One criticism of nutrient profiling is that it has been difficult to validate nutrient profile models as there is 'no gold standard' against which to compare their scores or classifications. One method of validation is to examine the health outcomes associated with consumption of foods that pass a nutrient profile model. There have been a small number of cohort studies that have found that higher consumption of foods categorised as 'healthy' by a nutrient profile model is associated with health benefits. For example, a study using a UK-based cohort found that greater consumption of foods categorised as healthier (by the Ofcom model [45]) were associated with a reduction of risk in all-cause mortality and cancer mortality [157].

Another method of validation is to compare the nutrient profile models' evaluations of healthiness to the evaluations by nutritionists. For example, Scarborough et al (2007) applied eight nutrient profile models to a database of 120 foods and compared the ranking of foods, as determined by each nutrient profile model, to scores and rankings allocated by nutritionists. The study found good agreement between the models and between the models and the nutritionist although cautions against this being a sole method of validation as there are wide variations in how nutritionists evaluate a food's nutritional composition [158].

Nutrient profiling and health-related claims

With regard to food labelling, nutrient profiling has been used in both regulatory and voluntary contexts. For example, health symbols are symbols on food labelling that aim to help consumers identify healthier foods that are supported by a nutrient profile model. Within Europe, a well-recognised health symbol is the Nordic Keyhole [159, 160]. Similar health symbols have also been developed by non-government organisations and commercial groups. For example, the Heart Symbol was developed by the Finnish Heart Association and the Finnish Diabetes Association [161]. Commercial and private health symbols include Kraft's 'Sensible Solution' [162] and the 'Choices International' scheme [106].

Nutrient profiling is also used for the regulation of health-related claims in some countries such as Australia and New Zealand [47] and the USA [163]. In Regulation (EC) 1924/2006 [38], the European Commission stated that it would use a nutrient profile model to regulate health-related claims so that only foods that pass the model are permitted to carry a health-related claim. However, this part of the 2006 regulation has not been implemented. The European Commission is currently evaluating whether a nutrient profile model "…is necessary to…avoid a situation where nutrition or health claims mask the overall nutritional quality of a food." (page 10 [164]).

Previous research

A review of studies testing the validity of nutrient profiling models [165] identified 18 studies that compared the scores or classifications of nutrient profile models, fourteen of which compared nutrient profile models used for the advertising of foods to children, nutrient summary systems (for example, traffic light labelling), health logos, and/or nutrient profile models used for research purposes. Just four studies compared multiple nutrient profile models used for regulation of health-related claims [166-169]. However, one study compared

the models' potential impacts on children's diets [166], two studies compared categorisations of foods carrying health-related claims but only within one food group (bakery products [167] and dairy products [168]), and the final study tested two models using a sample of foods commonly consumed in healthy diets and foods consumed in less healthy diets [169].

There have not been any studies that have just compared nutrient profile models used (or proposed for use) for the regulation of health-related claims by applying the models to a database of foods where most food categories are represented and where there is data available for both nutrient composition data and health-related claim data.

It is important to measure whether nutrient profile models agree with one another as you would expect nutrient profile models that were designed for the same purpose to categorise foods in a similar way. If nutrient profile models categorise foods in different ways, i.e. there is low agreement between the models, then the choice of nutrient profile used for the regulation of health-related claims may have a major impact on how the regulation is delivered. Previous research suggests that there are wide variations in how different nutrient profile models categorise foods, even when the models have the same purpose. For example, Scarborough et al [170] applied eight nutrient profile models that were designed to regulate the TV advertising of foods to children and found that the percentage of commercials/foods permitted by each model ranged from 2% to 47% and there was low agreement between the models.

The strictness of nutrient profile models used for the regulation of health-related claims is also an important issue as the strictness of any model will affect how many foods are allowed to carry health-related claims, which may in turn affect their impact on dietary intake.

Research questions

The research questions for this chapter are:

1. How do nutrient profile models that are used or that have been proposed for use in regulating health-related claims vary with respect to strictness (i.e. the percentage of foods that would be allowed to carry the health-related claim)?
2. How well do the nutrient profile models agree with each other in regards to which foods should carry health-related claims?
3. What impact would the use of three nutrient profile models have on the current prevalence of health-related claims?

Methods

The methods for sampling the foods, data extraction and categorisation were discussed in Chapter 3. The collection of nutritional data from the food label and the supplementation of data with data from the UK Nutrient Databank (and the appropriateness of doing this), was discussed in Chapter 5 (p130, p145-146).

In this chapter the methods for the following steps are discussed

- Categorising foods into food categories used by nutrient profile models
- Assessing the strictness of models and agreement between models
- Measuring the impact of nutrient profile models on the prevalence of health-related claims

Description of nutrient profile models used in this chapter

Three models used (or proposed for use) for the regulation of health-related claim were applied to the database of foods; the Food Standards Australia New Zealand's Nutrient

Profiling Scoring Criterion (FSANZ NPSC, [47]), the United States of America Food and Drug Administration model (US FDA model, [163], and a model proposed for use in the EU ([171] – Appendix F). Two of these models, the FSANZ NPSC and US FDA model, were chosen as they were identified in the WHO catalogue of nutrient profile models [172] as models developed by governments with the intended application of regulating health claims. Two additional models were also identified as such; the Healthier Choice Symbol developed by the Singapore Government [173] and the SAIN LIM model developed by the French Food Safety Agency [174]. However, the Singaporean model would have been difficult to apply as it contains different nutritional criteria for 105 food groups, applying the model would involve categorising foods into one of 105 food groups which would have taken a considerable amount of time. The French Food Safety Agency model was not applied as it is no longer is proposed for use.

The FSANZ NPSC

The FSANZ NPSC was implemented in Australia and New Zealand in Standard 1.2.7 – Nutrition, health and related claims [47]. This model was also used in the previous chapter. A description of the model is given in pages 130-132.

The United States of America Food and Drug Administration (The US FDA) model

The US FDA model has been used since 2001 [163]. The model is applicable to health claims as defined in Chapter 3 i.e. a claim for the effect of a nutrient or ingredient on a health outcome, whether explicit or implied.

The model that was applied in this chapter was that described in the General Requirement for Foods Carrying Health Claims [163]. There are additional criteria for specific types of claims, for example there are criteria for the use of the words 'healthy' [147]. In this chapter I apply

the model for the general requirements of foods carrying health claims but not the rules relating to specific claims.

The US FDA model is a threshold model whereby if a food exceeds any of the thresholds it is disqualified from making a health claim. The US FDA model assesses the levels of nutrients per serving size rather than per 100g of the food (as with the FSANZ NPSC).

Like the FSANZ NPSC, the US FDA model is a category-specific nutrient profile model. There are three food categories; Foods, Meal products, and Main dishes. Main dishes and Meal products are defined in 21CFR101.13 Nutrient content claims – general principles [147]. For example, Meal products must contain at least three 40g portions, and Main dishes must contain 40g, from two or more of the following food groups:

- Bread, cereal, rice, and pasta
- Fruit and vegetables
- Milk, yogurt, and cheese
- Meat, poultry, fish, dry beans, eggs, and nuts

In the US FDA model, Foods must contain ≤ 13g of total fat, ≤ 4g of saturated fat, ≤ 60mg of cholesterol, and ≤ 480mg of sodium per reference amount customarily consumed/per labelled serving size. For foods consumed in quantities of ≤ 30g then the nutrient levels for 50g of the food are assessed instead.

The thresholds for Main dishes are 50% higher than the thresholds for 'Foods', i.e. Main dishes must contain ≤ 19.5g of total fat, ≤ 6g of saturated fat, ≤ 90mg of cholesterol, and ≤ 720mg of sodium per labelled serving size. Whereas the thresholds for Meal products are doubled – Meal products must contain ≤ 26g of total fat, ≤ 8g of saturated fat, ≤ 120mg of cholesterol, and ≤ 960mg of sodium per labelled serving size.

In the US FDA regulation it states that foods that carry health-related claims must make a positive contribution to the overall diet. Foods carrying health claims must contain >=10% of

the Reference Daily Intake or Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fibre, per serving.

The model proposed for use in the EU

Whilst a nutrient profile model for the use of regulating health-related claims was never finalised, the European Commission did draft at least five versions of a nutrient profile model. The European Commission circulated these draft nutrient profile models in 2007, June 2008, October 2008, February 2009, and March 2009. These drafts were circulated to various stakeholders in order to gain feedback on the model. In this chapter I apply the version of the model dated 17th March 2009 (Appendix F, [171]) - the most recent version of the model.

The proposed EU model is a category-specific model with 15 food categories each with different thresholds for sodium, saturated fat, and total sugars. The thresholds for each food group are set per 100g/ml, foods that exceed one threshold would not be permitted to carry health-related claims.

Some of the categories have additional conditions for using health-related claims. For example, to be considered as a 'fruit and vegetable (or a fruit and vegetable product) foods must contain at least 50g fruit and/or vegetables. Some of the conditions require data on serving sizes and/or reference other ingredients. For example, to be considered as a 'Ready meal, soup, and sandwich' foods must have a serving size of at least 200g, and at least two portions of 30g from two or more of the following groups; fruit, vegetables and/or nuts cereals, meat, fish, and/or milk.

Under the proposal the following foods would be able to carry health-related claims even if they do not comply with the model:

- fruits, vegetables, and seeds, in any form (except oils), that do not have any added sugars, sodium, or fat,
- meats, fish, and eggs (as long as they are not breaded, processed, or in sauces),
- milks with 3% or less fat, eggs (not breaded, in sauces, etc.),
- honey, food supplements, table top sweeteners,
- high fibre breads that contain 3g or more fibre per 100g or at least 1.5g fibre per 100kcal,
- cough drops, chewing gum, dextrose tablets.

The following foods are not covered by the regulation:

- cereal-based foods and baby foods intended for infants and young children,
- foods intended for use in energy restricted-diets for weight regulation,
- infant formulae and follow-on formulae,
- dietary foods for special medical purposes
- salt.

Database of foods

The development of the database of foods used for the analyses in this chapter is described in Chapter 3. The database was designed to be representative of pre-packaged foods available to purchase in three store types (supermarkets, national stores, and discounter stores) across five countries (the UK, Germany, the Netherlands, Spain, and Slovenia). Using a stratified random sampling design 2034 foods were purchased (approximately 400 from each country) and the food labels were retained for data extraction. Along with the health-related claim data, the levels of the following nutrients (per 100g) were recorded from the food label; energy (kcal), protein, carbohydrates, total sugars, saturated fat, total fat, fibre, and sodium. The food serving size was also recorded.

Applying the nutrient profile models

Each of the models uses a different selection of nutrients in the model (Table 6.1). The only similarity across the three models is that all three models require data for saturated fat and sodium. The US FDA model requires data for vitamins and minerals, whereas the FSANZ NPSC and the EU Model rely on the use of macronutrients and sodium.

Data for the levels of calcium cholesterol, vitamin A, vitamin C, and iron were not recorded from the food labels therefore it would not be possible to apply the models unless the missing data were addressed. A food composition table, the UK Nutrient Databank [119], was used to supplement the nutritional data recorded from the food labels (described in Chapter 3). Each food was matched to a similar food in the databank. The nutritional data for the matched product was then merged with the food label data so that the food label data took precedence over the matched food data.

As the nutrient profile models are category-specific each of the foods in the database had to be categorised into the categories used by each model. This was done initially by the data collectors in each of the five countries and then adjusted for consistency and I made any necessary amendments. The foods were also categorised using the UK Eatwell Guide food groups [72] for the presentation of results.

Analyses

The models were applied in STATA v11 [75]. Stata syntax files (do-files) were written for each nutrient profile model and applied to the dataset described above. For each food, a set of three binary variables were derived which indicated whether or not the food was described as healthy by the nutrient profile model (i.e. whether the food would be allowed to carry a health-related claim). The STATA do-files for each model were checked by another researcher for any errors or inconsistencies.

Table 6.1 Data used in each of the nutrient profile models

	FSANZ NPSC	US FDA	EU Model
Number of categories in model	3	3	15
Data required for each model:			
Energy	✓		
Total sugars	✓		✓
Total fat		✓	✓
Saturated fat	✓	✓	✓
Sodium	✓	✓	✓
Protein	✓	✓*	
Fibre	✓	✓*	
Calcium	✓	✓*	
Cholesterol		✓	
Vitamin A		✓*	
Vitamin C		✓*	
Iron		✓*	
Fruit, vegetables, and nuts content	✓		
Base (for nutritional data)	Per 100g	Per serving *% RDI	Per 100g

The strictness of the nutrient profile models was assessed through examining the percentage of products that pass each nutrient profile model and 95% confidence intervals were calculated. The analyses were conducted on the full dataset and then stratified by food category.

The agreement between the nutrient profile models was assessed using Cohen's kappa [175] and the standard error. The results were interpreted using definitions proposed by Landis and Koch [105] where; <0.10 indicates no agreement, 0.10–0.20 as slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement.

The impact of the nutrient profile models on health-related claim prevalence was measured as the proportion of foods in the database that currently carry health-related claims and pass the nutrient profile models. For this, 95% confidence intervals were calculated and the analyses were conducted on the full dataset and stratified by food category.

Results

These results were calculated in STATA, the tables were exported to Excel for formatting.

Missing data

The missing data for each nutrient recorded from the food were discussed in Chapter 5 (Table 5.2), overall 22% of the data for the following nutrients energy, protein, carbohydrates, total sugars, saturated fat, total fat, fibre, and sodium, were missing from the food labels. As data for cholesterol, calcium, vitamin A, vitamin C, calcium, and iron were not recorded from the food label, all foods required supplementation for these data.

The missing data after the data were supplemented with the UK Nutrient Databank are presented in Table 6.2. Following supplementation, most foods (1811 foods, 89%) had enough nutritional data to be assessed by the three nutrient profile models. There were very few products that could not be assessed with the FSANZ NPSC (17 foods) and EU model (10 foods). In contrast, a larger number of foods could not be assessed by the US FDA model (208 foods, 10%), 93% of these foods (194 foods) could not be assessed due to missing portion size data, and the remaining 7% (14 foods) did not have data for cholesterol.

Table 6.2 Percentage and number of foods with missing data, by Eatwell Guide food group

Eatwell Guide food group	FSANZ NPSC	US FDA	EU Model
Potatoes, bread, rice, pasta or other starchy carbohydrates	0.1%, 3	0.3%, 7	0.1%, 3
Dairy or dairy alternatives	0%, 0	0.1%, 2	0%, 0
Foods high in fat and/or sugar	0.1%, 3	5.3%, 107	0.1%, 2
Beans, pulses, fish, eggs, meat and other protein	0.1%, 3	0.2%, 4	<0.0%, 1
Fruit and vegetables	0%, 0	1.1%, 23	0%, 0
Composite foods	0.2%, 5	0.1%, 2	<0.0%, 1
Miscellaneous	0.1%, 3	3.1%, 63	0.1%, 3
All foods	**0.8%, 17**	**10.2%, 208**	**0.5%, 10**

Strictness of nutrient profile models for the regulation of health-related claim regulation

The strictness of the three models was measured as the percentage of foods each model allows to pass (Table 6.3). The FSANZ NPSC allowed 43% of foods to pass, and the EU model allowed 47% of foods to pass whereas the US FDA model was the strictest model and passed 39% of foods.

The proportion of foods that passed each nutrient profile model varied by food group. The three models passed 20-28% of Foods high in fat and/or sugar. In contrast the models passed a high proportion of Fruits and Vegetables: the FSANZ NPSC passed 84% of this category, the EU model passed 75%, and the US FDA allowed 63%. A similar pattern across the models was seen for Potatoes, bread, rice, pasta or other starchy carbohydrates, where the models passed between 64 to 70% of foods, and for Dairy and alternatives where the percentage of foods that passed ranged from 57%-64%.

The US FDA model passed a lower proportion (28%) of Miscellaneous foods compared to the FSANZ NPSC which passed 46% and the EU model which passed 73% of such foods. The three models categorise some foods (such as tomato ketchup) within this category as unhealthy (53 foods). However, beverages such as mineral water, tea and coffee fail the US FDA model as they do not contain sufficient levels of protein, fibre, calcium, vitamin A, vitamin C, and/or iron to pass the model (49 foods).

Table 6.3 Percentage of foods that pass each nutrient profile models (n, %, 95% confidence intervals)

Eatwell Guide food group	**FSANZ NPSC**	**US FDA**	**EU Model**
Potatoes, bread, rice, pasta or other starchy carbohydrates	133, 70% (63%, 76%)	131, 70% (64%, 77%)	122, 64% (57%, 71%)
Dairy or dairy alternatives	93, 57% (50%, 65%)	87, 54% (47%, 62%)	104, 64% (57%, 72%)
Foods high in fat and/or sugar	150, 20% (18%, 23%)	180, 28% (25%, 32%)	177, 24% (21%, 27%)
Beans, pulses, fish, eggs, meat and other protein	130, 44% (38%, 50%)	110, 37% (32%, 43%)	173, 58% (52%, 63%)
Fruit and vegetables	133, 84% (77%, 89%)	86, 63% (55%, 71%)	120, 75% (69%, 82%)
Composite foods	97, 50% (43%, 57%)	49, 25% (19%, 31%)	101, 51% (44%, 58%)
Miscellaneous	127, 46% (40%, 52%)	60, 28% (22%, 34%)	201, 73% (68%, 78%)
All foods	**863, 43% (41%, 45%)**	**703, 39% (36%, 41%)**	**998, 49% (47%, 51%)**

The US FDA permitted 25% of Composite foods to carry a health-related claim, compared to the FSANZ NPSC and the EU model which both passed 50% and 51% respectively. Most of the ready-made pizzas in the database failed all three modes (21 foods) but a small number failed

the US FDA but passed the FSANZ NPSC (3 foods) or the EU Model (1 food). The US FDA model failed foods such as ready meals (28 foods), soups (19 foods) which the FSANZ NPSC and the EU model permitted.

Agreement between three models used for the regulation of health-related claims

The percentage agreement was measured as the proportion of foods that are categorised in the same manner by different models (Table 6.4). The percentage agreement between the models was highest for the agreement between the FSANZ NPSC and the EU model (81%) and lower between these models and the US FDA where there was agreement on 66% and 69% of foods. However, the percentage agreement does not take chance agreement into account therefore the agreement between the models was also assessed with Cohen's kappa statistic.

The kappa score can be interpreted using the definitions proposed by proposed by Landis and Koch [105] where a kappa score of <0.10 indicates "no agreement", 0.10-0.20 "slight agreement", 0.21-0.40 "fair agreement", 0.41-0.60 "moderate agreement", 0.61-0.80 "substantial agreement", and 0.81-1.00 "almost perfect agreement". There was substantial agreement between the FSANZ NPSC and the EU model. There was fair agreement between US FDA model and the EU model, and between the US FDA and the FSANZ NPSC.

Table 6.4 Agreement between nutrient profile models (percentage agreement, Cohen's kappa statistics [standard error])

	FSANZ NPSC	**US FDA**	**EU Model**
FSANZ NPSC	100%		
US FDA	69%. 0.35 (0.02)	100%	
EU Model	81% 0.62 (0.02)	66% 0.31 (0.02)	100%

Impact of nutrient profile models on health-related claim prevalence

The impact of the nutrient profile models on health-related claim prevalence was measured as the proportion of foods in the database that currently carry health-related claims and pass the nutrient profile models (Table 6.5). In Table 6.5 foods that currently carry a health-related claim but fail the model would not be considered as carrying a health-related claim.

Currently, 26% (95 % CI 24%, 28%) of foods carry a health-related claim, this would be reduced by 31% under the EU model, 38% under the FSANZ NPSC, and 50% by the US FDA. Using a nutrient profile model would reduce the health-related claim prevalence to 13% (95 % CI 11%, 14%) under the US FDA model, 16% (95 % CI 14%, 18%) under the FSANZ NPSC, and 18% (95 % CI 16%, 20%) under the EU model.

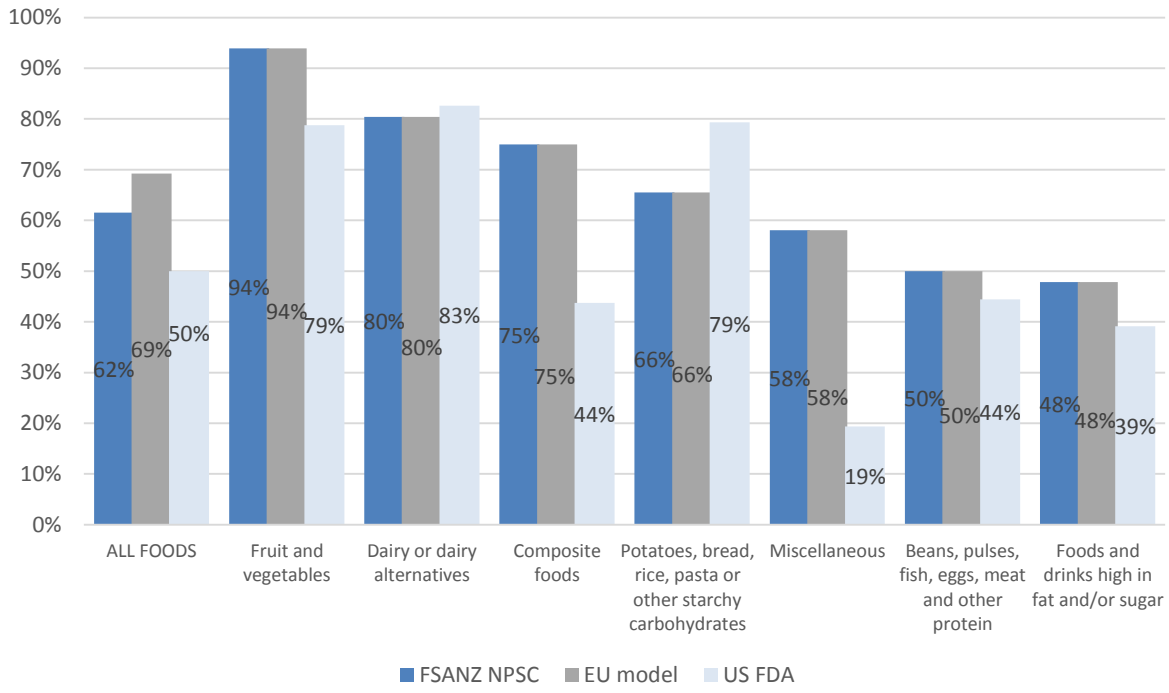
For some foods the prevalence would differ depending on which model was used. For example, there is 6% reduction in the prevalence of health-related claims for Fruits and vegetables under the FSANZ NPSC and the EU model but larger reduction under the US FDA (21% less). There are also large reductions for Miscellaneous foods where the prevalence is currently 31% (95% CI 26%, 37%) and is reduced to 18% (95% CI 14%, 23%) under the FSANZ NPSC and the EU model, and to 6% (95% CI 4%, 9%) under the US FDA model.

The impact of restricting health-related claims is greater in some categories than others. The prevalence of health-related claims for Beans, pulses, fish, eggs, meat and other protein foods would be halved under each of the models. Whereas for Dairy and dairy alternatives the prevalence would fall by 8-9%. Figuire 6.1 shows what percentage of current claims would be allowed under each nutrient profile model.

Table 6.5 Impact of nutrient profile models on health-claim prevalence (n, %, 95% CI)

	Health-related claim prevalence			
Eatwell Guide food group	**Current**	**Under the FSANZ NPSC**	**Under the US FDA**	**Under the EU model**
Potatoes, bread, rice, pasta or other starchy carbohydrates	29% (23%-36%)	19% (14%-18%)	23% (18%-30%)	19% (14%-25%)
Composite foods	16% (12%-22%)	12% (8%-17%)	7% (4%-11%)	12% (8%-17%)
Foods and drinks high in fat and/or sugar	23% (20%-26%)	11% (9%-13%)	9% (7%-11%)	11% (9%-13%)
Fruit and vegetables	33% (26%-41%)	31% (25%-39%)	26% (20%-33%)	31% (25%-39%)
Beans, pulses, fish, eggs, meat and other protein	18% (14%-22%)	9% (6%-13%)	8% (5%-11%)	9% (6%-13%)
Dairy or dairy alternatives	46% (39%-54%)	37% (30%-45%)	38% (30%-45%)	37% (30%-45%)
Miscellaneous	31% (26%-37%)	18% (14%-23%)	6% (4%-9%)	18% (14%-23%)
ALL FOODS	**26% (24%-28%)**	**16% (14%-18%)**	**13% (11%-14%)**	**18% (16%-20%)**

Figure 6.1 Percentage of health-related claims that would be permitted under the FSANZ NPSC, the US FDA model, and the EU Model



Discussion

Summary of results

In this chapter I applied three nutrient profile models used, or proposed for use, for the regulation of health-related claims on food labels. The FSANZ NPSC, the proposed EU model, and the US FDA model each permit less than half of foods in the database to carry a health-related claim. The US FDA is the strictest model where 39% of foods would be permitted to carry a claim, whereas the EU model and the FSANZ NPSC would permit 49% and 43% of foods to carry a health-related claim.

Of the foods carrying health-related claims, up to 50% would not be permitted in the EU if the 2006 regulation was supported by one of the three nutrient profile models tested in this chapter. The US FDA model is the strictest – only 50% of the foods currently carrying health-

related claims would be permitted to do so under the US FDA model, 62% would be permitted under the FSANZ NPSC, and 69% permitted under the proposed EU model.

The three models were strictest towards Foods high in fat and/or sugar and most lenient towards Fruits and vegetables. The three models allowed between 21-28% of Foods high in fat and/or sugar and 63-68% of Fruit and vegetables to carry health-related claim. The FSANZ NPSC and the EU model tend to agree on which type of foods should carry health-related claims, but there is weak agreement between these models and the US FDA model.

Comparison with other literature

Comparisons with other literature are difficult as there have only been a small number of studies that compared the FSANZ NPSC and the US FDA and one that have included the proposed EU model. Studies that have compared the FSANZ NPSC and US FDA use different samples of foods that are not comparable to the database used in this study.

Trichterborn et al (2011a) tested the Ofcom model (the foundation for the FSANZ NPSC) and the US FDA model on 200 fine bakery products such as cookies and cakes etc. [167]. Trichterborn found that the FSA model allowed 12% of products to pass whereas the US FDA permitted 37% to pass. In the analyses presented in this chapter I found smaller differences between how the FSANZ NPSC and US FDA categorised Foods high in fat and/or sugar; the FSANZ NPSC permitted 21% whereas the US FDA permitted 28%. However, the Trichterborn sample of foods only contained fine bakery products with health-related claims or information. When restricting our sample to Foods high in fat and/or sugar that carried health-related claims, I found that FSANZ NPSC permitted 48% and the US FDA permitted 39%.

In a similar study Trichterborn et al (2011b) compared the Ofcom model and the US FDA models categorisations of 300 dairy products carrying health-related claims and information

and found the Ofcom passed 58% of foods and the US FDA passed 68% of foods [168]. In our study I found that FSANZ NPSC passed 58% of Dairy and dairy alternatives products and the US FDA passed 54%. When to restricted to foods carrying health-related claims 80-83% passed. However, these differences may be due to the inclusion of products that contain health-related information (whereas our sample focuses on claims), and because in our sample the Foods high in fat and/or sugar category included non-bakery items such as confectionery.

Other studies that compared multiple nutrient profile models have found a wide variation in the agreement between models. For example, using a sample of 125 indicator foods (identified as foods regularly consumed in Europe), Azais-Braesco et al. [176] found that the correlation scores between four different nutrient profile models ranged from 0.64 to 0.79. However, that study examined the correlation between different models' rankings of foods nutritional quality. Whereas in this chapter I examined the agreement between the categorisations produced by nutrient profile models. However, I also found a wide variation in the kappa scores, ranging between 0.31-0.69.

Similarly, using a sample of 378 foods identified through a food frequency questionnaire, Drenowski et al [177] found the correlation between 15 nutrient profile models ranged from 0.11 to 0.99 with most models showing a strong correlation with one another. However, this study is not directly comparable as it involved different nutrient profile models, only one of which was used in the current study (the NPSC), on a different populations of food.

Implications for policy and research

The findings of this study may be of interest to the European Commission who are currently evaluating whether a nutrient profile model "…is necessary to… avoid a situation where nutrition or health claims mask the overall nutritional quality of a food." (page 10, [164]). Not all foods carrying health-related claims pass the nutrient profile models. Of foods carrying

health-related claims 38% fail the FSANZ NPSC, 31% fail the proposed EU model, and 50% fail the US FDA model. One possible implication of this finding is that a nutrient profile model may be required to prevent foods with an unfavourable nutritional profile carrying health-related claims. However, the results from the previous chapter found that, on average, the foods that carried health-related claims had significantly lower levels of: energy, protein, total sugars, total fat, and saturated fat, and significantly higher levels of fibre.

These findings from this chapter also suggest that the choice of nutrient profile model is important as there are differences in how models categorise foods. Whilst the models may be similarly strict, allowing between 39-49% of all foods in the database to pass, the models would impact the prevalence of health-related claims differently. This may affect the nutrient intake and subsequently the health of the population - the potential impact of using these models to regulate health-related claims is explored further in chapter 7.

Strengths and limitations

This analysis was conducted on a unique database of pre-packaged foods available to purchase in five EU countries. The application of the nutrient profile models was completed using Stata syntax files, which are available for further use upon request

A limitation of this study is the reliance on food composition tables (i.e. the UK Nutrient Databank) to supplement the incomplete nutritional information recorded from food labels. Doing this meant that most foods could be tested by the models and the validity analyses (discussed in Chapter 5) demonstrated that the nutritional information were generally well correlated to the foods in the UK Nutrient Databank.

In this chapter I used Cohen's kappa to assess the agreement between different models' categorisations of healthiness. Some researchers argue that Cohen's kappa can be an

unreliable statistic particularly when a nutrient profile model is a very strict or very lenient model. Some researchers proposed a Prevalence-Adjusted Bias-Adjusted Kappa (PABAK)[178] to adjust for this. As the three models used in this chapter were not very strict (i.e. allowing approximately 50% of foods to pass), I did not feel this was appropriate. If used PABAK resulted in very similar scores: FSANZ NPSC and FDA kappa = 0.35, PABAK = 0.38, and FSANZ NPSC and EU kappa = 0.62, PABAK = 0.62.

This study highlights the need for more validation studies of nutrient profile models. Whilst comparing multiple nutrient models can highlight the similarities and differences between the models it does not inform us which model is best as there is no gold standard with which to make a comparison to. Previous studies have compared the results of models to evaluations by nutritional experts (e.g. [158]). However, this is still problematic as the opinion of nutrition experts is to some degree subjective and there are often disagreements between nutrition experts.

Randomised controlled trials (RCTs) are often regarded as the ideal way to evaluate the impact of an intervention. In the case of nutrient profiling, evaluating its impact could take the form of an RCT in which participants are randomised to either receiving the intervention – e.g. greater consumption of foods categorised as healthy by a nutrient profile model, or to the control condition – e.g. 'normal' consumption of foods. The impact of nutrient profiling could then be measured in the change of biological indicators such as weight and/or health outcomes such as incidence of diseases. However, such studies are very difficult to conduct for many reasons. For example, it would be very difficult to get participants to adhere to the experimental diet for long enough, or ensure an adequate consumption of such foods, to observe any measurable differences in outcomes. There are also numerous other factors that could impact upon health. So far, such a study hasn't been completed.

There have been prospective cohort studies that measure the health status of individuals that consume a greater proportion of foods that pass a nutrient profile model and compared this to the health status of individuals that eat fewer foods that pass a nutrient profile model. However, these studies have had mixed results.

Twos studies in France found that higher consumption of foods categorised as healthier by the Ofcom model was associated with health benefits. Adriouch et al (2016, [179]) used data from a cohort of 6500 participants, examining six days of dietary records completed during the first two years of the study. The Ofcom model was used to evaluate the participants' diets through creating a dietary index for each individual, where a higher dietary index indicated a less healthy diet. The health outcomes of the participants were then followed over 12 years. The study found that people with a higher dietary index (i.e. consumed more foods that are categorised as less healthy by the Ofcom model) had an increased risk for developing cardiovascular disease. In a similar study, using the same cohort, Donnenfield et al (2015) found that a higher dietary index was associated with an increased cancer risk [180].

A study using a UK-based cohort suggested that foods identified as healthier have stronger associations with health outcomes than foods identified as less healthy. Masset et al (2015, [157]) used data from the Whitehall II cohort, and found that greater consumption of foods categorised as healthier (by the Ofcom model) were associated with a reduction of risk in all-cause mortality and cancer mortality, but not CHD. There was also no association between foods defined as less healthier.

Summary and next steps

In this chapter I measured the strictness and agreement between three nutrient profile models used, or proposed for, for the regulation of health-related claims. I then modelled the impact of using each nutrient profile model on the prevalence of health-related claims. It is

difficult to assess the impact of nutrient profiling on health and/or the impact of using a nutrient profile model for regulating health-related claims. This cannot be achieved without also considering the effect of health-related claims on purchases (Chapter 2), the prevalence of health-related claims (Chapter 4), and the nutritional quality of food carrying health-related claims (Chapter 5). In the next chapter I combine the findings from the previous chapters to model the effect of health-related claims on health outcomes and how this may (or may not) be improved with the use of nutrient profile models.

7. Modelling the effect of health-related claims on health outcomes

Summary

The effect of health-related claims on health outcomes is unclear. In this chapter I construct a model to estimate the effect of health-related claims on health outcomes. The model incorporates data that was presented in previous chapters together with a pre-established disease risk model. The findings presented in this chapter highlight the need for more data on the nutritional composition and health-related labelling data of pre-packaged foods.

Introduction

In the previous chapter I examined the strictness and agreement between different nutrient profile models. The models were similar in terms of strictness (i.e. the proportion of foods that 'pass' the model), the FSANZ NPSC permitted 43% (95% CI 41%, 45%) of foods to pass, the US FDA passed 39% (95% CI 36%, 41%), whilst the EU model passed a slightly higher proportion (49%, 95% CI 47%, 51%) of foods. However, the agreement between the models on which types of foods should be allowed to carry claims differed. There was substantial agreement between the FSANZ NPSC and the EU model (kappa 0.62, standard error 0.02) but weaker agreement between the US FDA model and the FSANZ NPSC (kappa 0.35, standard error 0.02) and the EU Model (kappa 0.31, standard error 0.02). In this chapter I model the potential impact of using different nutrient profile models for the regulation of health-related claims in terms of changes in nutrient intakes and the subsequent changes in mortality rates in the UK.

Approximately 26% of foods carry health-related claims (Chapter 4), and foods that carry claims have, on average, a slightly more favourable composition than foods that do not carry

health-related claims (Chapter 5). Foods that carry health-related claims are more likely to be chosen than foods without health-related claims (Chapter 2). However, it remains unclear whether any of these differences translate into differences in health outcomes.

Foods that carry health-related claims only have a slightly more favourable composition than foods do not carry health-related claims with (absolute) differences of less than 1g/100g for protein, carbohydrate, fibre, and sodium. However, even a small dietary change can have large health effects when scaled up to a population level. Furthermore, if a nutrient profile model were to be used to restrict health-related claims, thus increasing the nutritional differences, the health outcomes might be further improved.

There has not been a health impact assessment of the regulation of health-related claims (Regulation (EC) 1924/2006, [38]) nor of the potential impact of using a nutrient profile model to underpin the regulation. It has been assumed that the regulation of health-related claims with a nutrient profile model would have a positive impact, if any impact at all, through the restriction of less healthy foods. However, in a scenario where health-related claims increase purchases of foods that have a more favourable nutritional composition than foods without claims, it is possible that restricting the number of foods that carry claims could have negative health effects. Therefore a health impact assessment is crucial. In this chapter I estimate the effect of health-related claims on health outcomes by modelling the effects of different health-related claim scenarios on the diet and then using an established disease scenario model to model the health outcomes associated with these changes.

Background

Previous research into the impact of health-related food labelling

There have been a small number of studies that examine the effect of nutrition labelling on diet and/or health outcomes. Some studies have measured the effect of nutrition labelling on

health outcomes by comparing the health status of nutrition label users to that of non-users [181-183]. However, the measure of health varied between studies e.g. (self-reported) type-2 diabetes, hypertension, and high cholesterol levels [181] and BMI [182, 183]. Also, these studies largely had small sample sizes and involved self-reported data so are at risk of response bias (e.g. self-report bias and/or selection bias). Label-use may also introduce confounding as label-users may be more health-conscious than non-label users – for example, Mohelbalian, Cernusca, & Aguilar (2012) found that health-related claims had a greater effect on health-conscious compared to less-health conscious consumers [32].

To the best of my knowledge there have been no studies that examine the impact of health and nutrition claims, present on food labels in the UK, on health outcomes. There has been a single study of one type of health-related claim (a health logo) and its impact on a single health outcome (blood cholesterol levels) in the Netherlands [184].

An alternative method of measuring the effect of health-related food labelling is to model the effect of different nutrient intakes associated with different labelling scenarios. Modelling studies allow us to examine the population effects of interventions where traditional study designs such as RCTs would be impractical, and/or unethical.

Modelling health outcomes

Non-communicable disease (NCD) modelling involves examining different behaviours/risk factors ('inputs'), such as dietary behaviour, and the associated risk of developing and/or dying from a disease ('outcomes'). NCD modelling can be used for a variety of purposes including to inform decision-making (e.g. modelling cost effectiveness of different interventions/polices such as taxes on less healthy foods and/or subsides on healthier foods [185]), and estimating future disease incidence and mortality trends [186].

In this chapter, I build upon a pre-established NCD scenario model, the Preventable Risk Integrated ModEl (PRIME, [62]) to model the impact of nutrient intakes associated with different food labelling scenarios on UK mortality rates.

PRIME estimates the number of deaths averted for 24 health outcomes, these are grouped into the following categories, cardiovascular disease (CVD), diabetes, cancer, chronic obstructive pulmonary disease (COPD), kidney disease, and liver disease. This model has been used in 11 published studies to estimate the number of deaths averted or delayed under different conditions. For example, for the UK it was estimated that 33000 deaths per year would be avoided if UK dietary recommendations were met [11].

Research questions

The research questions for this chapter are:

1. What is the current effect of health-related claims on population-level NCD mortality in the UK?

2. What would be the effect on population-level mortality if a nutrient profile model was used to underpin the legislation so that only foods that pass the model could carry a claim?

Methods

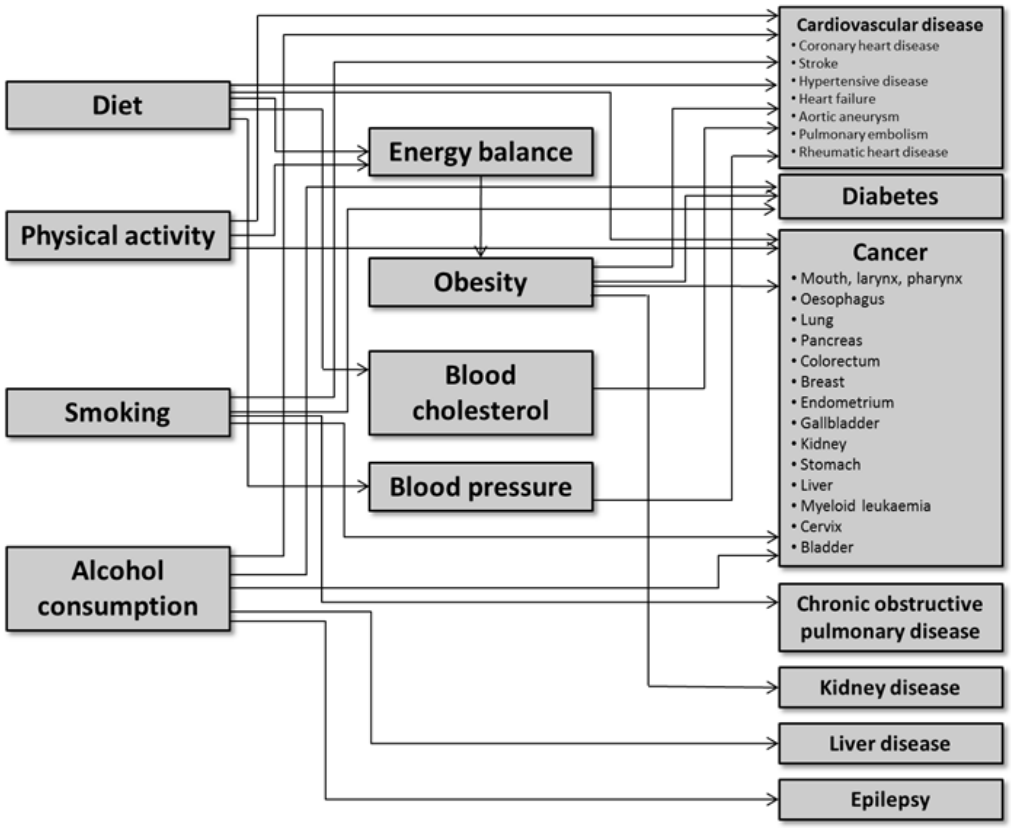
PRIME

PRIME links four behavioural risk factors (diet, physical activity, tobacco smoking, and alcohol consumption) to NCD mortality. These links can be direct, e.g. smoking is directly associated with CVD, or they can be mediated by three factors; body weight, blood cholesterol, and/or blood pressure. The schematic diagram of the model can be seen in Figure 7.1.

The links between the risk factors and the health outcomes were derived from a series of meta-analyses of studies examining the impact of changes in risk factors on disease outcomes. Each link represents the relative risk (RR)/probability of a disease occurring in a population where the exposure is present (or at higher levels) relative to when it is not present (or lower levels). For example, for each 106 grams per day increase of vegetable consumption there is an 11% reduction in risk (RR 0.89, 95% CI 0.83-0.95) in CHD. The relative risks used to characterise the links between the diet components and health outcomes are given in Appendix G. The components of diet included in PRIME are; fruit, vegetables, fibre, cholesterol, total fat, saturated fat, monounsaturated fat, poly-unsaturated fat, salt, and energy intake.

PRIME estimates the number of deaths that could be delayed or averted in the first year following an intervention due to population changes in the prevalence of these behavioural risk factors. PRIME examines the current distribution of these risk factors and the levels of different diseases within a population and compares these to the distribution of the behavioural risk factors in a counterfactual scenario. PRIME then models the changes in the annual number of deaths based upon the differences between the baseline and counterfactual scenario, using population impact fractions (PIFs) [3, 187]. In this chapter, I calculate the change in the nutritional quality of the diet as a result of the health-related claim scenarios, and translate this change into NCD mortality outcomes using the PRIME model.

Figure 7.1 Schematic diagram of PRIME [62]



Data Sources

To answer the research questions for this chapter, the following information is required:

- the effect of health-related claims on food purchases (Chapter 2),
- the prevalence of health-related claims (Chapter 4),
- the difference in nutritional composition of foods that carry health-related claims and those that do not (Chapter 5),
- the expected difference in nutritional composition of foods if health-related claims were only permitted on foods that pass a nutrient profile model (Chapters 5 and 6),
- the average population intake of nutrients, and
- information about the population (i.e. demographics and mortality rates).

The data sources are discussed in greater detail in Chapter 3, pages 90-94. A brief description is given below.

Population data

Population nutrient intake

The population nutrient intake data are required to measure the current/baseline distribution of nutrient intake within the population. These data were taken from the Living Costs and Food (LCF) survey (2015, [120]) and the National Diet and Nutrition Survey (NDNS, 2008-2012 [10]). This is discussed on pages 90-93.

UK population estimates

The estimates for the population age and sex data were taken from the Annual Mid-Year Population Estimates (2013, [124]) . These estimates are derived from the census which is conducted in the UK every ten years, with updated estimates for the population data produced each June updates between every census survey. The mortality data were collated from data for the registered deaths for England and Wales [125], Scotland [126], and Northern Ireland [127] . This is discussed on pages 93-94.

Health-related claim data

As the following information was presented in earlier chapters, only a brief summary is provided below.

The effect of health-related claims on diet

A systematic review was conducted to estimate the effect of health-related claims on dietary choices (Chapter 2). The review considered studies that involved a controlled intervention, where the experimental group(s) included an exposure to a product with a health-related

claim and the control group involved exposure to an identical product without a health-related claim. To be included in the review, studies had to measure, either at an individual or population level; actual or intended product choices, purchases, and/or consumption. Odds ratios (ORs) for the likelihood of choosing a product and the percent change in purchase and/or consumption (along with 95% confidence intervals [95% CI]) were calculated using Stata V11 [75].

Meta-analyses of 17 studies found that products carrying health-related claims were 75% (OR 1.75, 95% CI 1.60, 1.91) more likely to be chosen than identical products without a health-related claim. Analyses by food group found that odds ratios differed by food group - these odds ratios were used to parametrise the model. For example, Beans, pulses, fish, eggs, meat and other protein products carrying health related claims were more than twice as likely (OR 2.42, 95% CI 1.87, 3.12) to be chosen (relative to identical products not carrying health-related claims), whereas very minor differences were seen on Composite foods (OR 1.06, 95% CI 0.91, 1.24).

Health-related claim prevalence

The prevalence of health-related claims, that is the proportion of foods that carry at least one health-related claim, was estimated using a randomly sampled selection of pre-packaged foods. Products were collected in the UK, Germany, the Netherlands, Slovenia, and Spain. The study was powered to detect a 10% difference in the prevalence of health-related claims between countries, 400 products were sampled from each country. The nutritional information and health-related claim information was recorded from the food label.

The results of this survey were presented in Chapter 4. The main findings were that, overall, 26% (95% CI 24%, 28%) of pre-packaged foods carried a health-related claim, and that there were significant differences between food groups in the prevalence of health-related claims.

Nutritional quality of foods carrying claims

The nutritional information for the following nutrients was recorded from the food label: energy (kcal per 100 grams), protein, carbohydrates, total sugars, total fat, saturated fat, fibre, and sodium (in grams per 100 grams). The mean levels of nutrients were compared for foods that carry health-related claims and foods that do not. In this chapter the means are used to create a ratio of nutrient quality (NQR) for foods that carry claims relative to foods that do not.

The impact on the average nutritional quality of foods carrying health-related claims if health-related claims were only permitted on foods that pass the Food Standards Australia New Zealand's Nutrient Profiling Scoring Criterion (FSANZ NPSC, [47]) was measured in Chapter 5. In this chapter the impact of two other regulatory models; the US FDA model [163] and the latest version of the nutrient profile model proposed for use by the European Commission are also assessed [171]. Whilst there are many nutrient profile models that are used for various aspects of health-related labelling, e.g. summary indictor systems such as the Health Star rating system [148], these three models were chosen as they are currently used, or proposed for use to regulate health-related claims

For the analyses involving the nutrient profile models, the mean levels of nutrients were calculated for foods that pass the nutrient profile model and carry health-related claims, and for foods that do not carry claims and/or fail the nutrient profile model. As described above these means were then used to create nutrient quality ratios (NQRs).

Modelling the nutrient intake

In this modelling exercise the estimated average nutrient intake is divided into the nutrient intake from foods carrying health-related claims and the nutrient intake from foods that do not carry health-related claims. The division of nutrients is scaled according to the odds ratios presented in Chapter 2 and the difference in nutritional quality between foods that carry

health-related claims and foods that do not that is presented in Chapter 5. In total, eleven models were executed, the parameters of each model are presented in Table 7.1 and a summary is provided below.

Baseline scenario:

This scenario, depicted in Figure 7.2, reflects the current nutrient intake in the UK and the current UK mortality rates/burden of disease. The estimates for the health-related claim prevalence, nutrient composition, and odds ratios for the likelihood of choosing a product when a health-related claim is present (relative to when a health-related claim is not present) are stratified by the Eatwell Guide food groups.

This scenario assumes that the current nutrient intake and NCD mortality rates reflect a situation where, (depending on the food group), 22-67% of foods carry at least one health-related claim and that these foods have the nutritional qualities estimated in Chapter 5.

The LCF data on the sales of products is divided into sales of products with health-related claims and sales of products without health-related claims. This is achieved through solving mathematical equations combining the LCF sales data with the Odds Ratios and the health-related claim prevalence estimates, so that the sum of the sales of products with health-related claims and the sales of products without claims is equal to the total sales of products (as estimated by the LCF). Similarly, mathematical equations are solved that combine the NQRs with the sales of foods carrying and not carrying health-related claims, so that the nutrients from foods with and without health-related claims can be estimated, and such that the total nutritional quality of the baseline diet matches that shown in the LCF dataset. The equations and steps taken to disaggregate the LCF survey data is presented in Figure 7.3. This allocation of sales and nutrients between foods that carry health-related claims and those that do not is required to model the remaining scenarios.

Figure 7.2 Baseline scenario

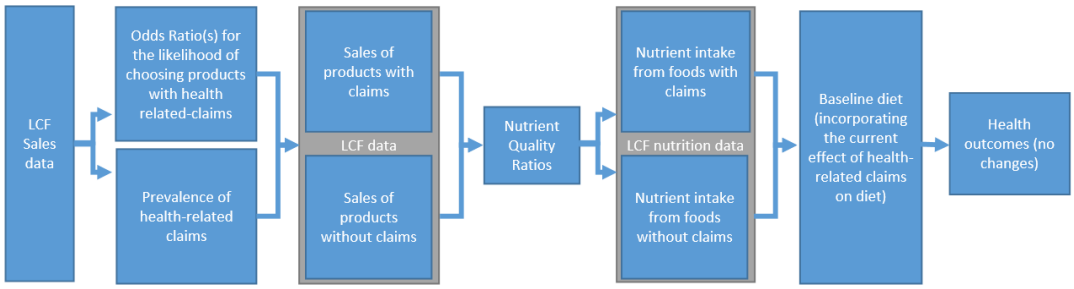
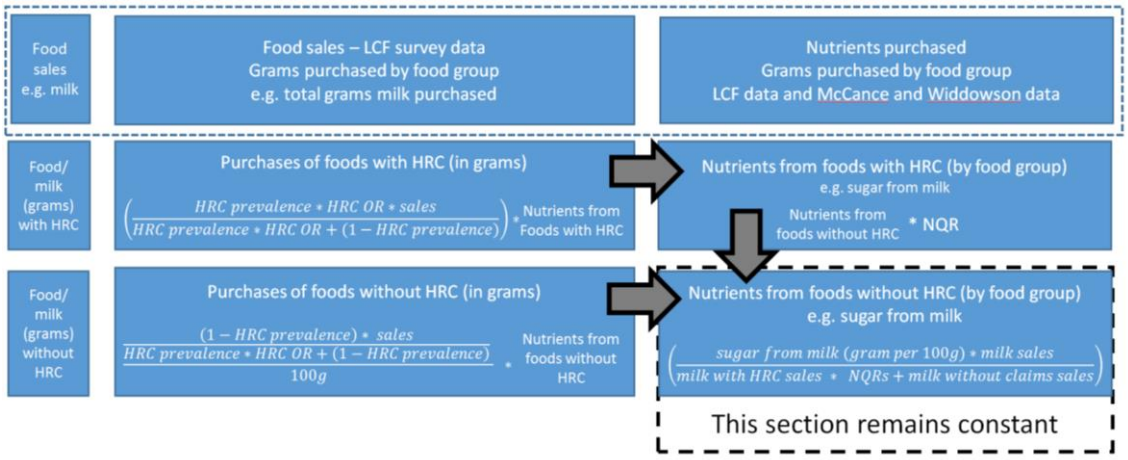


Figure 7.3 Equations used to disaggregate the LCF survey data



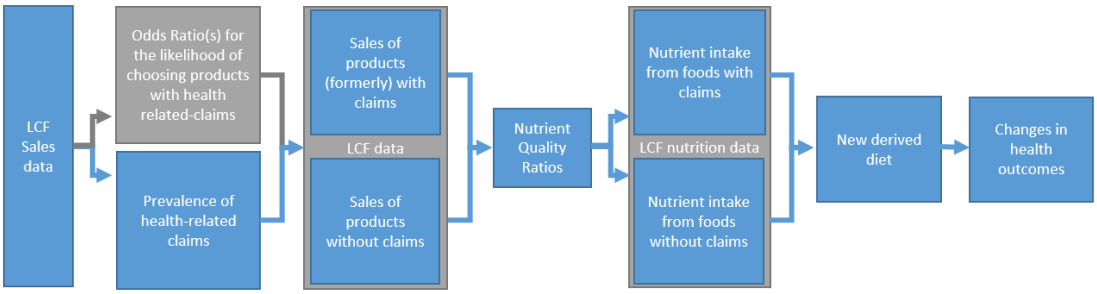
Model 1: 'Heath-related claims removed'

In this model the scenario modelled is that health-related claims are removed from food labels (Figure 7.4). The foods that previously carried health-related claims are still available to purchase but no longer receive the increased boost in intake that is assumed in the baseline model. To model this the odds ratios are set to 1 (i.e. no effect) as indicated in Figure 7.4 by the greying of the relevant box in the flow diagram. The sales of foods with and without claims are re-calculated so that foods with claims are equally likely to be chosen as foods without claims. However, the differential nutritional quality of foods that carry and do not

carry health-related claims (estimated in the baseline scenario) is retained, so that a new total nutritional quality of the diet is estimated as the sum of the nutritional quality of foods carrying health-related claims and the nutritional quality of foods not carrying health-related claims, weighted by the estimated sales of these foods.

As health-related claims are already present on foods it is assumed that any impact that they may have upon diet - and subsequently, health outcomes - are already in effect. In Model 1 these effects are neutralised, and any changes (relative to the baseline scenario) in health outcomes are therefore assumed to be due to health-related claims. The first aim of this chapter is to estimate current effect of health-related claims on population-level NCD mortality in the UK. The results of Model 1 can be inverted to estimate the current impact of health-related claims – i.e. how many deaths are currently averted by health-related claims.

Figure 7.4 Model 1

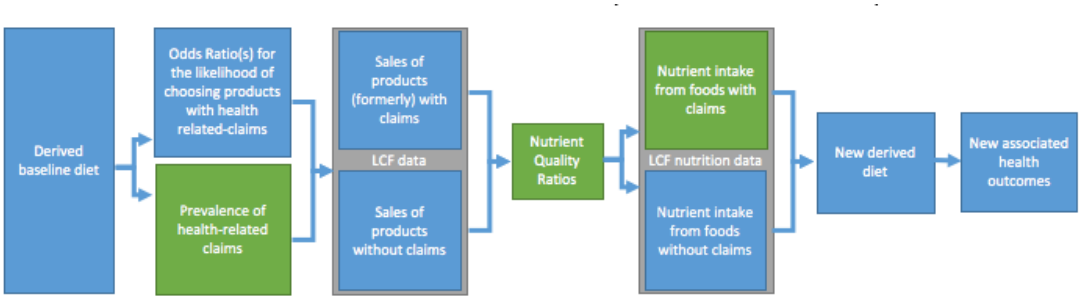


Models 2a, 3a, 4a: 'Health-related claims restricted'

In Models 2a, 3a, and 4a (Figure 7.5), the use of health-related claims is restricted using a nutrient profile model so that only foods that pass the FSANZ NPSC (Model 2a), the US FDA model (Model 3a), or the nutrient profile model proposed by the EU (Model 4a) may carry health-related claims. In these Models foods that currently carry health-related claims but fail

the nutrient profile model(s) are considered not to carry a health-related claim any longer. For example, in Chapter 6, the impact of using the FSANZ NPSC to restrict health-related claims was assessed. Overall, 26% of foods carry a health-related claim, however 38% of these foods fail the FSANZ NPSC, therefore the expected prevalence of health-related claims under the FSANZ NPSC would be reduced to 16%.

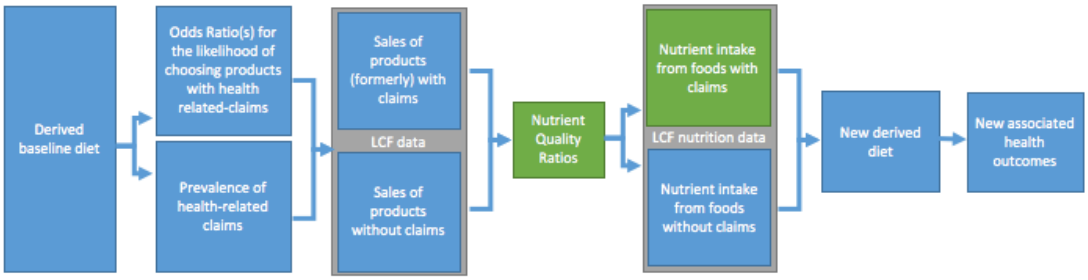
Figure 7.5 Models 2a, 3a, 4a



In each Model the health-related claim prevalence and the nutrient quality ratios (NQRs) are re-calculated to produce specific results for each nutrient profile model being tested. The calculated nutrient composition (per 100g) of foods not carrying claims remains the same as in the baseline scenario, and is multiplied by the new NQRs to achieve the nutrient composition (per 100g) of foods carrying claims. Maintaining the nutrient composition of foods not carrying claims at the same level as the baseline scenario assumes that foods that previously carried health-related claims but are no longer permitted to do so change to these levels i.e. they do not improve or worsen the nutrient composition (per 100g) of foods not carrying claims. Crucially, these scenarios assume that food manufacturers do not reformulate any foods so that they pass the nutrient profile models. Instead, foods that currently carry health-related claims but fail the nutrient profile models are assumed to remain in the market, but without a

health-related claim (and hence no additional sales boost associated with the health-related claim). Further, it is assumed that, as a response to the loss of the health-related claim, food manufacturers no longer attempt to maintain the nutritional superiority of these foods, and their nutritional composition therefore changes to the mean levels of foods that currently do not carry health-related claims.

Figure 7.6 Models 2b, 3b, 4b



Models 2b, 3b, 4b: 'Reformulating foods that carry health-related claims'

In these scenarios (Figure 7.6), the use of health-related claims is restricted with a nutrient profile model, but the health-related claim prevalence is maintained at current levels. Thus, these models suggest that manufacturers of foods that currently carry claims but fail to meet a nutrient profile model would chose to reformulate these foods rather than lose the health-related claim – hence, the prevalence of claims remains the same as in the baseline scenario but the nutritional quality of foods that carry claims increases to the levels in Models 2a, 3a and 4a.

Model assumptions

For all models it is assumed that there will be no change from the baseline scenario in physical activity levels, smoking, and/or alcohol consumption. The health-related claim estimates were derived from a cross-sectional survey of health-related claims in 5 EU countries (this is discussed further in the sensitivity analyses).

It is assumed that the overall consumption of food groups does not change and any changes in consumption are made within food categories. For example, in the scenario where health-related claims were removed, the total amount (in grams) of confectionery foods consumed does not change, but there would be changes in the consumption of confectionery items that (previously) carried health-related claims and the amount of confectionery foods that did not carry health related claims, therefore nutrient intakes would differ from the baseline scenario.

Whilst PRIME does allow for age and sex specific nutrient intake estimates, in this modelling exercise it is assumed that health-related claims have the same effect on males and females, and this effect does not differ by age group. This is due to the lack of age and sex data available for the meta-analyses of the effect of health-related claims on dietary choices (Chapter 2) and the lack of age and sex-specific purchase data from the LCF survey.

The collection of the nutritional composition data for this project was described in Chapter 5. PRIME requires data on the amount of mono-unsaturated fatty acids, poly-unsaturated fatty acids, and cholesterol for each scenario. The estimated population intake of these nutrients is provided in the LCF survey therefore we can estimate how the intake of these nutrients will change on the basis of how the overall intake of food groups changes. However, this information is only provided on food labels on a voluntary basis and was not recorded from the food labels when it was present in our representative survey of pre-packaged foods. Therefore, in this modelling exercise I assume that the average levels per 100g of these

nutrients do not differ between foods that carry health-related claims and foods that do not carry health-related claims.

The parameters for each model are outlined in Table 7.1. In this table 'health-related claim prevalence' refers to the percentage of foods that carry health-related claims thereby receiving the additional boast in sales as represented by the OR for the effect of health-related claims on dietary choices.

Table 7.1 Parameters used to model the impact of health-related claims (HRC) on health outcomes

Food group	Impact of HRC on dietary choices (ORs)	Health-related claim prevalence							
				'Restricted' models			'Restricted & reformulated' models		
		Baseline	1 HRC removed	2a FSANZ NPSC	3a US FDA	4a EU model	2b FSANZ NPSC	3b US FDA	4b EU model
Potatoes, bread, rice, pasta or other starchy carbohydrates	1.17 (1.60-1.91)	29% (23%-36%)	0%	19% (14%-18%)	23% (18%-30%)	19% (14%-25%)	29% (23%-36%)	29% (23%-36%)	29% (23%-36%)
Composite foods	1.06 (0.91-1.24)	16% (12%-22%)	0%	12% (8%-17%)	7% (4%-11%)	12% (8%-17%)	16% (12%-22%)	16% (12%-22%)	16% (12%-22%)
Foods and drinks high in fat and/or sugar	1.35 (1.09-1.66)	23% (20%-26%)	0%	11% (9%-13%)	9% (7%-11%)	11% (9%-13%)	23% (20%-26%)	23% (20%-26%)	23% (20%-26%)
Fruit and vegetables	1.92 (1.56-2.35)	33% (26%-41%)	0%	31% (25%-39%)	26% (20%-33%)	31% (25%-39%)	33% (26%-41%)	33% (26%-41%)	33% (26%-41%)
Beans, pulses, fish, eggs, meat and other protein	2.42 (1.87-3.12)	18% (14%-22%)	0%	9% (6%-13%)	8% (5%-11%)	9% (6%-13%)	18% (14%-22%)	18% (14%-22%)	18% (14%-22%)
Dairy or dairy alternatives	1.25 (1.22-1.27)	46% (39%-54%)	0%	37% (30%-45%)	38% (30%-45%)	37% (30%-45%)	46% (39%-54%)	46% (39%-54%)	46% (39%-54%)
Miscellaneous	1	31% (26%-37%)	0%	18% (14%-23%)	6% (4%-9%)	18% (14%-23%)	31% (26%-37%)	31% (26%-37%)	31% (26%-37%)

Uncertainty analyses

Uncertainty analyses allow us to quantify how uncertain we are of our point estimates once the variance in each of the parameters is taken into account. Monte Carlo analyses are commonly used in modelling studies to measure the uncertainty in a model and show what the most-likely result is. Monte Carlo analyses operate by selecting a set of values which follow the probability distributions of each parameter in the model (one set of values is called an iteration of the model), multiple iterations are computed and the results/outcomes for each iteration is recorded, the 2.5^{th} and the 97.5^{th} quartiles are then treated as the uncertainty intervals.

Parametric uncertainty

In this chapter the Monte Carlo analyses were set at 10000 iterations and incorporated the uncertainty around the following variables:

- the prevalence of health-related claims
- the mean nutrients per 100g for foods that do and do not carry health-related claims,
- the ORs for the impact of health-related claims on dietary choices
- the RR for the epidemiological parameters used in PRIME

Sensitivity analyses

In these analyses a number of decisions were made on how best to construct the model such as using food group-specific odds ratios and nutritional composition data rather than using averages across all food groups. Sensitivity analyses allow us to assess the impact of these decisions on the final results. In each of the sensitivity analyses the scenario being modelled was the removal of health-related claims from food labels (Model 1).

Sensitivity Model 1- Health-related claim data source

Sensitivity Model 1 (SM1) assesses the effect of using health-related claim prevalence estimates and nutritional composition data specific to the UK rather than the equivalent estimates using data from all five countries covered in the health-related claim survey; the UK, Denmark, Germany, the Netherlands, Spain, and Slovenia. The aim of this chapter is to model the health outcomes in the UK, therefore PRIME is populated with UK population data for both the mortality rates and nutrient intake. Given this, it may have been most appropriate to restrict the health-related claim estimates to the subsample of UK products within the database. However, due to the relatively small sample sizes, particularly in regards to *the 'Health-related claims restricted'* models, data from five countries were used to regain some statistical power.

Sensitivity Model 2 – Specificity of parameters (level of analyses)

Sensitivity Model 2 (SM2) assesses the sensitivity of the results to the specificity of the parameters. Analyses were conducted at two levels; 'food group' and 'all foods'. The 'food group' levels refers to analyses where results are stratified by Eatwell Guide food groups whereas the 'all foods' level refers to analyses where estimates were made for the whole sample of foods (i.e. not stratified by food group). The food group level of analyses allows for more specificity in the estimates, this is important as the previous analyses in Chapters 4 and 5 show that the health-related claim prevalence rate differs by food group and that there are differences between the average nutritional compositions between the food groups. However, the study was not powered for analyses at the food group level, therefore the food groups are not equally represented in the final database of products. At the food group level, there is increased specificity but as there are fewer products behind each estimate there is less statistical power, thus larger uncertainty intervals would be expected in the modelling results.

Sensitivity Models 3 and 4 – eligibility and consideration of fruit and vegetable content

Previous modelling studies have found that small changes in fruit and vegetable consumption can lead to large changes in mortality rates [11]. The fruit and vegetable data used in this study may be less consistent than the nutrient data as during the data extraction phase of the health-related claim survey, the data collectors were instructed to record the amount of fruit and vegetables present in a food, however this was not always provided so estimates were made to the nearest 10%. As discussed in Chapter 5, each food collected in the survey was matched to a similar food in the UK Nutrient Databank. These data were used to supplement the collected data so that most foods could be assessed by the nutrient profile models applied in Chapters 5 and 6.

For Models 1-5 the fruit and vegetable content of a food was only taken into consideration in PRIME when the fruit and vegetable content of the food was ≥80%. Sensitivity Models 3 and 4 assess the effect of this. In Sensitivity Model 3 (SM3) all fruit and vegetables are taken into account in the model. In Sensitivity Model 4 (SM4) the fruit and vegetable consumption does not change from the baseline model (i.e. no fruit and vegetable are taken into account by the model).

Sensitivity Model 5 - Obesity and PRIME

Previous studies using PRIME have found that the model is sensitive to changes in the population distribution of BMI, which itself is sensitive to changes in daily energy intake. There is some evidence to suggest that people engage in compensatory dietary behaviours when they increase their energy expenditure (e.g. [188]), for example consuming more calories as a reward for exercising. It is unclear whether there is a similar response with regard to the changes in dietary behaviour being modelled in this chapter. The meta-analyses presented in Chapter 2 explores whether the presence of health-related claims affects consumption of

identical foods, but cannot determine how consumption of other foods (e.g. from other food categories) may change.

In the analyses presented in this chapter two versions of PRIME are conducted, in one version the obesity component of the model is disabled i.e. changes in energy intake are not taken into account in this model, and in the second set of results - Sensitivity Model 5 (SM5) - the obesity component is enabled.

Sensitivity Model 6: Odds Ratios of the effect of health-related claims on dietary choices

The Odds Ratios used to parametrise the model were derived from a meta-analysis of experimental studies where participants were asked to choose between a product with a health-related claims and an identical product without a health-related claim. These types of studies are conducted in artificial settings and may potentially over-estimate the true effect of health-related claims in the real world. In these studies other factors which may influence choices such as branding, prices, location etc. are often not adjusted for in the analyses. Therefore a sensitivity analysis was also conducted in which each of the ORs were each reduced and increased by 50%, and then using ORs of 1.10, and 1.20, consistently across categories.

Results

The health-related claim parameters were derived from analyses conducted in STATA and the modelling exercise was conducted in Excel.

The impact of health-related claims on the average population nutrient intake

In this section the point estimates from the models are discussed, the uncertainty intervals shall be discussed separately in the Sensitivity analyses section. The impacts of different health-related claim scenarios on the population nutrient intake are presented in Table 7.2. This table shows the average purchases per person, per day, by food category and the associated nutrient intake.

In the baseline scenario, foods carrying health-related claims made-up 37% of the total purchases, and contributed 29% (559kcal) of the total number of kcals purchased (1907kcal). Relative to the baseline scenario, in the three restricted scenarios (Models 2a, 3a, 4a) there are reductions in the proportion of purchases of foods that carry claims ranging between a 10% reduction (Model 2a and Model 4a) to a 13% reduction under Model 3a.

When health-related claims are removed (Model 1) from foods there is an average increase of 18kcal/d in the total energy intake, a 2g/d increase in total fat and saturated fat, a 3g/d increase in total sugar, and smaller changes are seen in regards to protein (+0.5g/d), carbohydrate (-0.5g/d). There is reduction in the amount of fruit (-11g/d) but an increase in vegetables (+6g/d).

Under the '*health-related claims restricted*' models (Models 2a, 3a, 4a) there is a 42-47% reduction in energy from foods carrying health-related claims. Under Model 2a, there were small changes in protein (+0.3g/d), fibre (-0.2g/d), larger changes in carbohydrate (-6g/d), total sugars (-2.2g/d), fat (+1.6/d), and a 3-4g/d increase in fruit and vegetables.

Under Model 3a, there was a small reduction in carbohydrate (-2g/d), fibre and total fat (-0.2g/d), and larger increases in saturated fat (+1.8g/d) and total sugars (+6g/d). There was a 5g/d reduction in fruit and a 2g/d increase in vegetables. Under Model 4a there was a reduction in total fat (-1.4g/d), and increases in saturated fat (+1.3g/d), carbohydrates

(+2.0g/d), and total sugars (5.6g/d) and small reductions in fruits (-0.2g/d) and vegetables (-0.4g/d).

Under the '*Reformulating foods that carry health-related claims*' models (Model 2b, 3b, 4b) there are reductions in energy intake of 90kcal/d (Model 2b), 60kcal/d (Model 4b), and 54kcal/d (Model 3b). There are reductions in the total fat content under all three models, with the largest reduction seen under 3b (8.7g/d). There are also large reductions in the total sugar intake seen under Models 2b and 4b (-11g/d) but a 2.8g/d increase under Model 3b. The fruit intake and vegetable intake increases by 5.5 and 3.3g/d respectively under Model 2b, under Model 3b there is a 1.4g/d increase in fruit and a 1.3g/d reduction in vegetables, and under Model 4b there is a small reduction in in fruit (-0.6g/d) but a large increase in vegetables (7.1g/d).

Nutrient intakes by food group in each scenario are provided in Table 7.3.

Figure 7.7 Purchases of foods that carry health-related claims (HRC) and foods that do not under each scenario

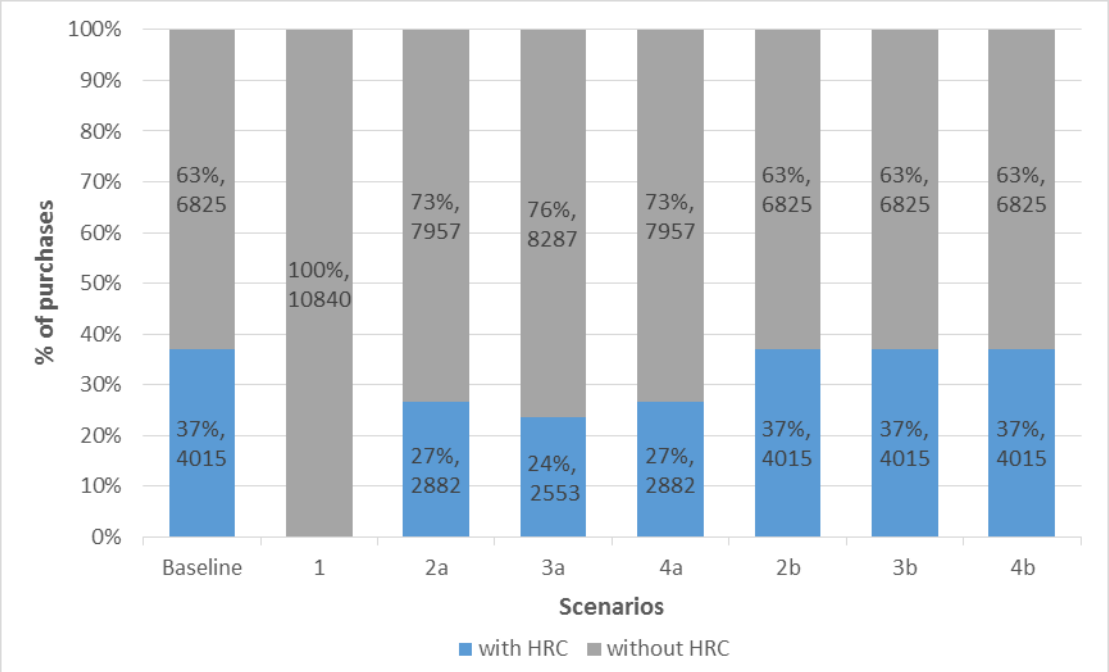


Table 7.2 Nutrient intake (per day) under each health-related claim (HRC) scenario

Model	Nutrients from foods...	% of total sales	Energy (kcal)	Protein (g)	Carbohydrate (g)	Total sugars (g)	Total fat (g)	Saturated fat (g)	Mono-unsaturated fat (g)	Poly-unsaturated fat (g)	Fibre (g)	Sodium (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
Baseline	with HRC	37%	558.9	21.2	78.4	35.4	19.3	5.5	9.2	4.3	5.7	0.5	75.1	91.9	54.5
	without HRC	63%	1347.8	44.9	155.5	70.5	60.4	25.5	20.1	9.9	6.8	1.8	149.0	59.3	76.6
	Total	100%	1906.8	66.1	233.8	105.9	79.7	31.0	29.4	14.2	12.6	2.3	224.1	151.2	131.1
1	with HRC	30%	444.4	15.8	65.1	28.2	14.4	4.2	6.9	3.3	4.5	0.4	50.3	62.6	37.1
	without HRC	70%	1480.1	50.8	168.2	78.3	67.0	28.2	22.4	10.9	7.7	2.0	173.8	77.4	100.0
	Total	100%	1924.5	66.6	233.3	106.4	81.4	32.5	29.4	14.2	12.3	2.4	224.1	140.0	137.2
2a	with HRC	27%	299.2	13.6	45.8	20.3	9.5	2.0	5.4	2.5	4.5	0.2	46.1	93.2	55.3
	without HRC	73%	1589.2	52.8	182.0	83.3	71.9	30.4	24.0	11.7	7.8	2.2	178.0	61.8	79.8
	Total	100%	1888.4	66.5	227.8	103.7	81.4	32.4	29.4	14.2	12.3	2.3	224.1	154.9	135.1
3a	with HRC	24%	296.0	12.4	51.8	25.4	5.8	1.6	4.7	2.1	4.3	0.2	40.6	76.2	43.5
	without HRC	76%	1623.1	53.7	183.9	86.5	73.7	31.1	24.7	12.0	8.0	2.2	183.5	69.7	90.0
	Total	100%	1919.1	66.1	235.6	111.9	79.5	32.8	29.4	14.2	12.3	2.4	224.1	145.9	133.5
4a	with HRC	27%	323.1	13.7	53.8	28.1	6.5	1.9	5.4	2.5	4.3	0.2	46.1	89.2	50.9
	without HRC	73%	1589.2	52.8	182.0	83.3	71.9	30.4	24.0	11.7	7.8	2.2	178.0	61.8	79.8
	Total	100%	1912.2	66.5	235.9	111.5	78.4	32.3	29.4	14.2	12.1	2.4	224.1	151.0	130.7
2b	with HRC	37%	468.8	20.2	67.3	24.7	16.8	3.3	9.2	4.3	6.4	0.3	75.1	97.4	57.9
	without HRC	63%	1347.8	44.9	155.5	70.5	60.4	25.5	20.1	9.9	6.8	1.8	149.0	59.3	76.6

Model	Nutrients from foods...	% of total sales	Energy (kcal)	Protein (g)	Carbohydrate (g)	Total sugars (g)	Total fat (g)	Saturated fat (g)	Mono-unsaturated fat (g)	Poly-unsaturated fat (g)	Fibre (g)	Sodium (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
	Total	100%	1816.6	65.1	222.7	95.2	77.2	28.7	29.4	14.2	13.2	2.1	224.1	156.7	134.5
3b	with HRC	37%	504.4	20.7	80.6	38.2	10.7	3.0	9.2	4.3	6.1	0.3	75.1	93.3	53.2
	without HRC	63%	1347.8	44.9	155.5	70.5	60.4	25.5	20.1	9.9	6.8	1.8	149.0	59.3	76.6
	Total	100%	1852.3	65.6	236.0	108.6	71.2	28.4	29.4	14.2	13.0	2.2	224.1	152.6	129.8
4b	with HRC	37%	498.7	21.0	69.6	24.6	17.6	3.9	9.2	4.3	5.9	0.3	75.1	91.4	61.6
	without HRC	63%	1347.8	44.9	155.5	70.5	60.4	25.5	20.1	9.9	6.8	1.8	149.0	59.3	76.6
	Total	100%	1846.5	65.9	225.0	95.0	78.0	29.3	29.4	14.2	12.8	2.1	224.1	150.6	138.2

Table 7.3 Nutrient intake under different labelling scenarios, purchase averages g/ml per person, per week (LCF 2014)

Model	Food group	Purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
Baseline	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	421.4	12.8	5.7	1.5	84.8	6.4	5.3	0.55	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	152.8	8.0	8.0	2.7	13.1	2.0	0.7	0.33	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	687.6	6.2	37.8	14.7	86.1	59.3	1.8	0.63	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	102.1	2.7	1.1	0.2	21.9	20.0	3.3	0.04	0.3	0.4	0.3	1058.4	917.8
	Beans, pulses, fish, eggs, meat and other protein	929.2	260.0	22.3	17.1	5.5	4.7	1.6	1.1	0.50	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	192.5	12.5	9.6	6.1	14.9	14.6	0.0	0.22	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	90.4	1.8	0.6	0.2	8.4	2.0	0.3	0.08	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1906.8	66.1	79.7	31.0	233.8	105.9	12.6	2.35	29.4	14.2	224.1	1058.4	917.8
1	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	419.5	12.7	5.6	1.4	84.5	6.2	5.2	0.56	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	153.2	7.9	8.0	2.7	13.2	2.0	0.7	0.33	3.1	1.6	26.0	0.0	0.0

Model	Food group	Purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
	Foods and drinks high in fat and/or sugar	2840.2	697.8	6.4	38.5	15.3	86.5	61.0	1.8	0.64	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	107.0	2.7	1.3	0.3	21.7	19.3	3.4	0.05	0.3	0.4	0.3	980.0	960.1
	Beans, pulses, fish, eggs, meat and other protein	929.2	255.5	22.2	17.0	5.9	4.1	1.5	0.9	0.54	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	201.2	12.9	10.3	6.6	14.9	14.5	0.0	0.23	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	90.4	1.8	0.6	0.2	8.4	2.0	0.3	0.08	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1924.5	66.6	81.4	32.5	233.3	106.4	12.3	2.42	29.4	14.2	224.1	980.0	960.1
2a	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	408.6	13.0	5.0	1.3	83.1	4.5	5.2	0.56	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	151.8	7.8	8.0	2.7	12.9	1.9	0.7	0.33	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	690.5	6.3	39.3	15.7	83.4	59.8	1.7	0.61	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	100.6	2.7	1.0	0.2	22.3	20.3	3.3	0.04	0.3	0.4	0.3	1084.5	946.0
	Beans, pulses, fish, eggs, meat and other protein	929.2	256.6	22.1	17.2	5.7	4.1	1.4	1.0	0.49	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	198.7	12.9	10.4	6.7	14.5	14.0	0.0	0.23	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	81.7	1.6	0.5	0.2	7.6	1.8	0.3	0.07	0.2	0.1	0.8	0.0	0.0

Model	Food group	Purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
	ALL FOODS	10839.8	1888.4	66.5	81.4	32.4	227.8	103.7	12.3	2.33	29.4	14.2	224.1	1084.5	946.0
3a	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	416.2	12.6	5.5	1.4	83.9	5.6	5.1	0.54	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	159.0	8.2	8.4	2.9	13.6	2.1	0.7	0.35	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	704.4	6.8	38.2	16.0	86.7	64.8	1.9	0.64	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	108.8	2.9	1.2	0.2	23.3	20.9	3.4	0.05	0.3	0.4	0.3	1021.4	934.6
	Beans, pulses, fish, eggs, meat and other protein	929.2	244.1	22.0	15.7	5.7	4.3	1.4	0.8	0.53	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	195.2	11.9	9.9	6.4	15.4	15.1	0.1	0.21	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	91.4	1.8	0.6	0.2	8.3	2.0	0.3	0.08	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1919.1	66.1	79.5	32.8	235.6	111.9	12.3	2.39	29.4	14.2	224.1	1021.4	934.6
4a	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	414.0	12.6	5.5	1.4	83.7	5.3	4.8	0.55	1.8	1.6	2.6	0.0	0.0

Model	Food group	Purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
	Composite foods	556.5	158.0	8.4	8.3	2.8	13.4	2.1	0.7	0.33	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	695.8	6.7	37.4	15.6	86.3	64.1	1.9	0.62	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	107.3	2.9	1.1	0.2	23.6	21.4	3.4	0.04	0.3	0.4	0.3	1056.9	914.9
	Beans, pulses, fish, eggs, meat and other protein	929.2	243.1	22.0	15.5	5.6	4.5	1.4	0.8	0.52	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	196.4	12.0	10.0	6.4	15.4	15.1	0.1	0.21	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	97.6	2.0	0.6	0.2	9.0	2.1	0.3	0.07	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1912.2	66.5	78.4	32.3	235.9	111.5	12.1	2.36	29.4	14.2	224.1	1056.9	914.9
2b	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	411.3	13.2	4.9	1.2	83.3	4.6	5.9	0.52	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	148.5	7.8	7.8	2.6	12.5	1.9	0.7	0.32	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	637.3	5.5	36.7	13.6	78.3	50.9	1.6	0.53	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	99.8	2.7	1.0	0.2	22.3	20.4	3.3	0.04	0.3	0.4	0.3	1097.0	941.2
	Beans, pulses, fish, eggs,	929.2	261.1	22.0	17.3	5.1	4.5	1.4	1.3	0.43	7.3	2.9	124.8	0.0	0.0

Model	Food group	Purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
	meat and other protein														
	Dairy or dairy alternatives	1835.4	181.8	12.2	9.1	5.9	14.5	14.3	0.0	0.20	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	76.8	1.6	0.5	0.1	7.2	1.7	0.3	0.06	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1816.6	65.1	77.2	28.7	222.7	95.2	13.2	2.11	29.4	14.2	224.1	1097.0	941.2
	Potatoes, bread, rice, pasta														
3	or other starchy														
b	carbohydrates	1518.1	419.5	12.6	5.6	1.4	84.3	5.9	5.4	0.52	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	157.1	8.5	8.2	2.8	13.2	2.1	0.7	0.32	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat														
	and/or sugar	2840.2	648.4	6.4	32.7	13.3	84.4	59.9	2.1	0.57	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	106.9	2.9	1.1	0.2	23.7	21.6	3.4	0.04	0.3	0.4	0.3	1068.1	908.7
	Beans, pulses, fish, eggs,														
	meat and other protein	929.2	237.2	21.9	14.3	5.0	5.2	1.4	0.9	0.48	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	178.9	11.0	8.7	5.6	15.6	15.5	0.1	0.19	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	104.2	2.3	0.6	0.2	9.6	2.1	0.4	0.06	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1852.3	65.6	71.2	28.4	236.0	108.6	13.0	2.17	29.4	14.2	224.1	1068.1	908.7

Model	Food group	Purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
4b	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	413.1	12.9	5.0	1.2	83.8	4.7	5.6	0.50	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	150.2	7.9	7.9	2.7	12.7	1.9	0.7	0.32	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	651.8	5.7	37.7	13.9	79.8	51.4	1.6	0.53	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	100.2	2.7	1.0	0.2	21.7	19.7	3.3	0.04	0.3	0.4	0.3	1054.5	967.6
	Beans, pulses, fish, eggs, meat and other protein	929.2	253.5	22.5	16.5	5.1	4.3	1.4	1.1	0.46	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	187.3	12.3	9.3	6.0	14.4	14.1	0.0	0.21	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	90.3	1.8	0.6	0.2	8.4	1.9	0.3	0.06	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1846.5	65.9	78.0	29.3	225.0	95.0	12.8	2.12	29.4	14.2	224.1	1054.5	967.6

Health outcomes

The modelled impact of health-related claims on UK NCD mortality rates are presented in Table 7.4 (the full tables are provided in Appendix H). This table presents the number of deaths delayed or averted, so in this table negative numbers indicate that the number of deaths would be increased from the baseline scenario, and a positive number indicates that the number of deaths would be reduced.

The total number of deaths calculated from the baseline scenario is 283, 231 deaths. This represents the total number of deaths from the 24 health outcomes modelled by PRIME that are attributable to diet (listed in Figure 7.1 and in Appendix G).

When health-related claims are removed from food labels (Model 1), PRIME estimates that there will be an increase of 2808 deaths (95% UI -2993, 7392), a 1% increase in deaths from the baseline scenario. Around 85% of these additional deaths would be from cardiovascular diseases (primarily coronary heart disease and stroke). These increases would be mainly due to a reduction in fruit and vegetable consumption (1110 additional deaths, 95% UI -4605, 5146), and increases in salt consumption (648 additional deaths, 95% UI -109, 1924) and changes in the fatty acid composition of the diet (610 additional deaths, 95% UI -9, 1312).

Under the assumption that manufacturers of foods that currently carry health-related claims would not reformulate in order to maintain claim use, regulation of health-related claims with a nutrient profile model leads to an increase in deaths for all three nutrient profile models assessed here. Although the nutritional quality of foods that carry health-related claims increases, this is outweighed by the reduced prevalence (and hence reduced consumption) of such foods. Using a nutrient profile model to restrict claims would lead to a <1% increase in deaths compared to the baseline scenario. Using the FSANZ NPSC model to restrict claims would result in in an additional 258 (95% UI -6509, 8706) deaths (0.1% increase in deaths from the baseline), using the EU model would result in an additional 1189 deaths (95% UI -7431,

7584, 0.4% increase in deaths) –and using the US FDA model would result in an additional 1828 deaths (95% UI -7614, 5978, a 0.6% increase in deaths).

However, regulating health-related claims with a nutrient profile model and maintaining health-related claim prevalence at current levels (i.e. assuming manufacturers would reformulate foods so that the claim prevalence is maintained at current levels) leads to a <2% reduction in deaths from the baseline. The greatest number of averted deaths is observed with the FSANZ NPSC where 4374 deaths (95% UI -2569, 14009, a 1.5% increase in deaths averted) would be averted, followed by the US FDA model where 3763 (95% UI -3174, 13225, a 1.3% increase) and with the EU model where 3151 (95% UI -3783, 12296, a 1.1% increase) deaths are averted.

Sensitivity analyses

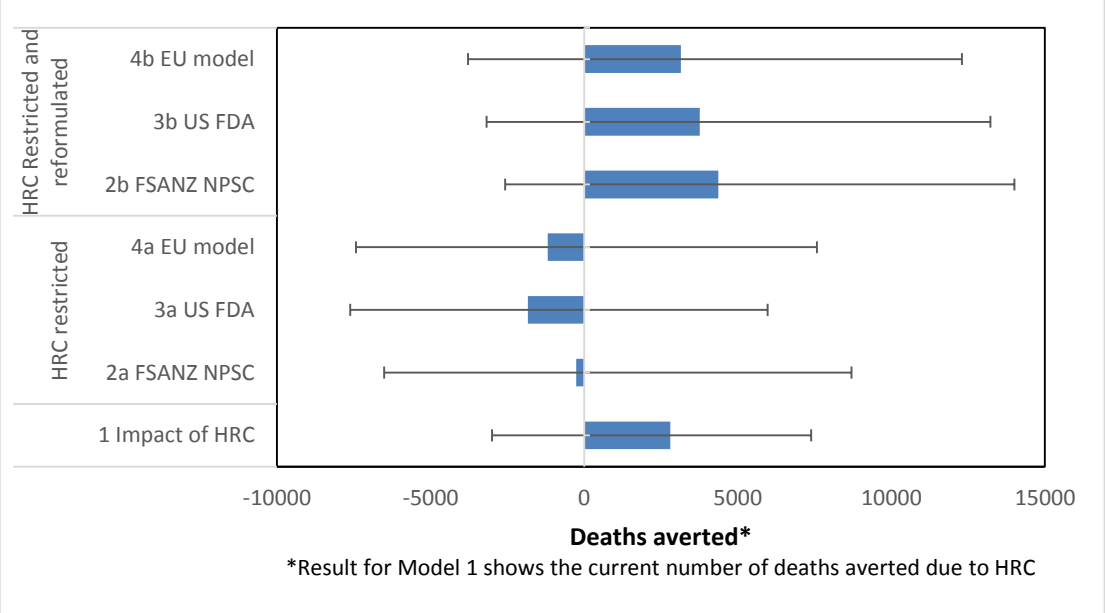
The results of the sensitivity analyses (Sensitivity Models 1-4) are presented in Tables 7.5 and 7.6, here the scenario being modelled is that health-related claims are removed from food labels.

Table 7.4 The impact of health-related claims, in different regulatory scenarios, on UK mortality from non-communicable diseases (95% Uncertainty Intervals)

Deaths averted or delayed:	***Impact of HRC (M1)***	**'Restricted' models**			**'Restricted & reformulated' models**		
		2a – FSANZ NPSC	**3a - US FDA**	**4a - EU model**	**2b – FSANZ NPSC**	**3b - US FDA**	**4b - EU model**
Total	*2808 (-2993, 7392)*	-258 (-6509, 8706)	-1828 (-7614, 5978)	-1189 (-7431, 7584)	4374 (-2569, 14009)	3763 (-3174, 13225)	3151 (-3783, 12296)
Male	*1514 (-1514, 3938)*	-277 (-3582, 4460)	-1019 (-4066, 3048)	-736 (-4096, 3905)	2363 (-1347, 7455)	2220 (-1457, 7162)	1743 (-1960, 6583)
Female	*1294 (-1483, 3466)*	19 (-2946, 4286)	-809 (-3523, 2915)	-453 (-3392, 3719)	2011 (-1259, 6533)	1543 (-1749, 6119)	1408 (-1843, 5795)
Deaths averted or delayed by cause:							
Cardiovascular disease	*2369 (-2340, 6225)*	-347 (-5565, 6946)	-1605 (-6440, 4702)	-1030 (-6256, 6183)	4078 (-1708, 12085)	3648 (-2103, 11352)	3136 (-2793, 10710)
Cancer	*439 (-840, 1464)*	89 (-1236, 2030)	-223 (-1403, 1433)	-159 (-1480, 1729)	295 (-1067, 2287)	115 (-1330, 2118)	15 (-1388, 2039)
Deaths averted or delayed by behavioural risk factor:							
Fruit and vegetables	*1110 (-4605, 5146)*	995 (-4737, 9177)	-572 (-5744, 6795)	476 (-5336, 8396)	1198 (-4729, 9478)	79 (-6190, 8817)	656 (-5394, 9068)
Fibre	*428 (-779, 1478)*	-366 (-1989, 2651)	-346 (-1899, 2107)	-788 (-2259, 1812)	982 (-1295, 5045)	627 (-1212, 3771)	319 (-1723, 3793)
Fats	*610 (-9, 1312)*	-1025 (-1768, -349)	-517 (-1051, 10)	-1006 (-1737, -332)	182 (-947, 1229)	1577 (715, 2593)	180 (-922, 1197)
Salt	*648 (-109, 1924)*	129 (-579, 1020)	-387 (-1230, 437)	121 (-634, 1095)	2052 (716, 3776)	1511 (387, 3034)	2016 (651, 3781)

Deaths averted or delayed:	*Impact of HRC (M1)*	'Restricted' models			'Restricted & reformulated' models		
		2a – FSANZ NPSC	**3a - US FDA**	**4a - EU model**	**2b – FSANZ NPSC**	**3b - US FDA**	**4b - EU model**
Deaths averted or delayed with Obesity enabled (Sensitivity Model 9)							
Total	*4141 (-2220, 9419)*	996 (-5632, 9519)	-2739 (-8873, 5246)	-1158 (-7861, 7965)	9450 (2468, 18851)	7084 (-278, 16140)	6795 (-203, 15755)

Figure 7.8 The impact of health-related claims, in different regulatory scenarios, on UK mortality from non-communicable diseases



Sensitivity analyses

The results of the sensitivity analyses (Sensitivity Models 1-4) are presented in Tables 7.5 and 7.6, here the scenario being modelled is that health-related claims are removed from food labels.

Table 7.5 Modelled nutrient intake for the sensitivity analyses, purchase averages g/ml per person, per week (LCF 2014)

Model	Food group	2014 purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
M1	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	419.5	12.7	5.6	1.4	84.5	6.2	5.2	0.56	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	153.2	7.9	8.0	2.7	13.2	2.0	0.7	0.33	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	697.8	6.4	38.5	15.3	86.5	61.0	1.8	0.64	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	107.0	2.7	1.3	0.3	21.7	19.3	3.4	0.05	0.3	0.4	0.3	980.0	960.1
	Beans, pulses, fish, eggs, meat and other protein	929.2	255.5	22.2	17.0	5.9	4.1	1.5	0.9	0.54	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	201.2	12.9	10.3	6.6	14.9	14.5	0.0	0.23	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	90.4	1.8	0.6	0.2	8.4	2.0	0.3	0.08	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1924.5	66.6	81.4	32.5	233.3	106.4	12.3	2.42	29.4	14.2	224.1	980.0	960.1
SM1	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	418.8	12.7	5.7	1.5	84.3	6.1	5.2	0.57	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	153.1	8.0	8.0	2.7	13.1	2.0	0.7	0.33	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	703.5	6.3	39.0	15.5	87.2	62.4	1.8	0.64	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	115.1	2.7	1.5	0.3	23.3	20.6	3.5	0.06	0.3	0.4	0.3	1004.9	951.8

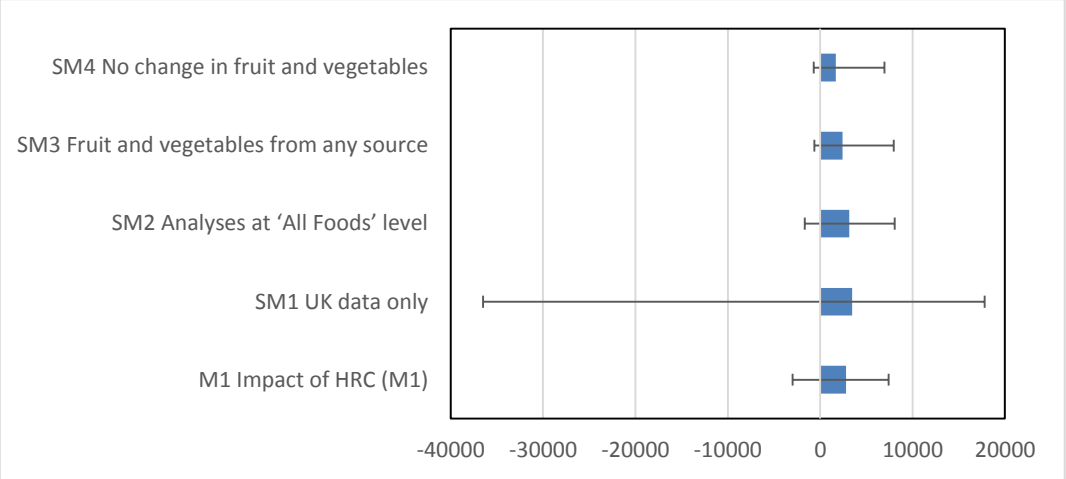
Model	Food group	2014 purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
	Beans, pulses, fish, eggs, meat and other protein	929.2	246.6	22.7	16.5	6.2	3.9	1.4	0.7	0.61	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	203.7	13.1	10.5	6.6	14.7	14.2	0.0	0.24	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	90.4	1.8	0.6	0.2	8.4	2.0	0.3	0.08	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1931.2	67.2	81.8	33.1	235.0	108.7	12.3	2.52	29.4	14.2	224.1	1004.9	951.8
SM2	ALL FOODS (CONDUCTED AT ALL FOODS LEVEL)	10839.8	1963.7	67.9	84.2	33.7	235.2	109.3	12.0	2.5	29.4	14.2	224.1	1017.3	955.1
SM3	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	419.5	12.7	5.6	1.4	84.5	6.2	5.2	0.56	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	153.2	7.9	8.0	2.7	13.2	2.0	0.7	0.33	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	697.8	6.4	38.5	15.3	86.5	61.0	1.8	0.64	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	107.0	2.7	1.3	0.3	21.7	19.3	3.4	0.05	0.3	0.4	0.3	997.2	960.0
	Beans, pulses, fish, eggs, meat and other protein	929.2	255.5	22.2	17.0	5.9	4.1	1.5	0.9	0.54	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	201.2	12.9	10.3	6.6	14.9	14.5	0.0	0.23	2.6	0.4	29.6	0.0	0.0

Model	Food group	2014 purchases	Energy (kcal)	Protein (g)	Total fat (g)	Saturated fat (g)	Carbohydrate (g)	Total sugars (g)	Fibre (g)	Sodium (g)	MUFAs (g)	PUFAs (g)	Cholesterol (mg)	Fruit (g)	Vegetables (g)
	Excluded/Miscellaneous	1187.1	90.4	1.8	0.6	0.2	8.4	2.0	0.3	0.08	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1924.5	66.6	81.4	32.5	233.3	106.4	12.3	2.42	29.4	14.2	224.1	997.2	960.0
SM4	Potatoes, bread, rice, pasta or other starchy carbohydrates	1518.1	419.5	12.7	5.6	1.4	84.5	6.2	5.2	0.56	1.8	1.6	2.6	0.0	0.0
	Composite foods	556.5	153.2	7.9	8.0	2.7	13.2	2.0	0.7	0.33	3.1	1.6	26.0	0.0	0.0
	Foods and drinks high in fat and/or sugar	2840.2	697.8	6.4	38.5	15.3	86.5	61.0	1.8	0.64	14.1	7.2	40.0	0.0	0.0
	Fruit and vegetables	1973.3	107.0	2.7	1.3	0.3	21.7	19.3	3.4	0.05	0.3	0.4	0.3	997.2	960.0
	Beans, pulses, fish, eggs, meat and other protein	929.2	255.5	22.2	17.0	5.9	4.1	1.5	0.9	0.54	7.3	2.9	124.8	0.0	0.0
	Dairy or dairy alternatives	1835.4	201.2	12.9	10.3	6.6	14.9	14.5	0.0	0.23	2.6	0.4	29.6	0.0	0.0
	Excluded/Miscellaneous	1187.1	90.4	1.8	0.6	0.2	8.4	2.0	0.3	0.08	0.2	0.1	0.8	0.0	0.0
	ALL FOODS	10839.8	1924.5	66.6	81.4	32.5	233.3	106.4	12.3	2.42	29.4	14.2	224.1	997.2	960.0

Table 7.6 The impact of health-related claims on UK mortality from non-communicable diseases (results for the sensitivity analyses models 1-4)

Deaths averted or delayed:	***Impact of HRC (M1)***	**SM1 UK data only**	**SM2 Analyses at 'All Foods' level**	**SM3 Fruit and vegetables from any source**	**SM4 No change in fruit and vegetables**
Total	*2808 (-2993, 7392)*	3459 (-36505, 17803)	3147 (-1662, 8070)	2425 (-625, 7964)	1693 (-692, 6952)
Male	*1514 (-1514, 3938)*	1905 (-18651, 9652)	1778 (-775, 4385)	1317 (-240, 4363)	991 (-225, 3876)
Female	*1294 (-1483, 3466)*	1554 (-17780, 8196)	1369 (-878, 3683)	1107 (-394, 3605)	702 (-460, 3100)
Deaths averted or delayed by cause:					
Cardiovascular disease	*2369 (-2340, 6225)*	3147 (-29493, 15710)	2858 (-1530, 7507)	2072 (-702, 7537)	1646 (-736, 6856)
Cancer	*439 (-840, 1464)*	313 (-7534, 2925)	289 (-419, 935)	353 (-195, 729)	47 (-21, 217)
Deaths averted or delayed by risk factor:					
Fruit and vegetables	*1110 (-4605, 5146)*	681 (-38594, 12176)	355 (-2901, 3038)	730 (-1610, 2491)	0 (0, 0)
Fibre	*428 (-779, 1478)*	415 (-4697, 2654)	762 (-233, 1809)	428 (-281, 1776)	428 (-204, 1772)
Fats	*610 (-9, 1312)*	815 (-867, 3214)	1015 (367, 1785)	610 (365, 1735)	610 (373, 1778)
Salt	*648 (-109, 1924)*	1527 (-406, 7039)	998 (-2204, 4916)	648 (-2132, 4960)	648 (-2072, 5012)

Figure 7.9 The impact of health-related claims on UK mortality from non-communicable diseases, (results for the sensitivity analyses)



The estimates for the current health-related claim prevalence and the nutritional quality ratios were based upon a sample of approximately 2000 foods from five EU countries (the UK, plus Germany, Denmark, Spain, and Slovenia). In Sensitivity Model 1 (SM1) the estimates for the health-related claim prevalence and the associated nutritional composition data are based on the products from the UK only, approximately 400 foods. In this sample the health-related claim prevalence is, overall, 10% higher with the greatest difference seen for fruits and vegetables where 67% of foods carry claims (compared to 33% of such foods from all five countries).

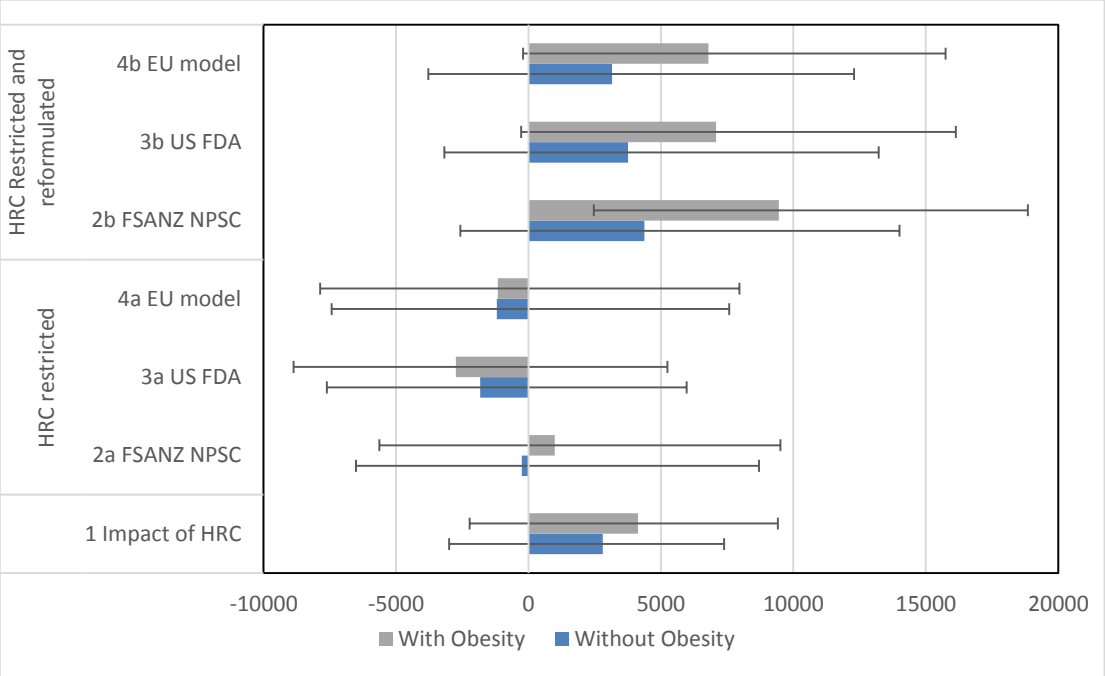
Under Sensitivity Model 1 removing health-related claims would result in 3459 additional deaths (95% UI -36505, 17803), this is 651 more than estimated under Model 1. Restricting the data to UK data results in much larger uncertainty intervals than when data from all five countries was used (Model 1). Under Model 1 the uncertainty intervals range from -2993 to 7392, these intervals are approximately a quarter of the breadth than those produced under Sensitivity Model 1.

Under Sensitivity Model 2 (SM2) the data analyses were conducted at the 'all foods' level, i.e. they were not stratified by food group. In this model the health-related claim prevalence estimate was 26% (95% CI 24%, 28%) and the odds ratio for the likelihood of choosing a food when a health-related claim was present (relative to when it is not) was 1.75 (95 CI 1.60, 1.91). In this model there are 3147 (95% UI -1662, 8070) deaths, 339 more deaths than when the analyses are conducted at the food group level. The uncertainty levels have a breadth of 9732 which is only slightly smaller than those from Model 1.

In the Models 1-5, fruit and vegetables are only considered as such if it is present in a food in an amount that is greater than 80%. In Sensitivity Model 3 (SM3) fruit and vegetables are considered regardless of the total content of fruit and/or vegetables in the food. This has a small impact to the results; there are 2425 deaths (95% UI -625, 7964), an increase of 383 deaths from Model 1. In Sensitivity Model 4 (SM4), the fruit and vegetable intake is kept the same as it is in the baseline scenario, this reduces the number of deaths by 1115 to 1693 (95% UI -692, 6952).

When a change in energy intake is taken into account (Sensitivity Model 5, SM5), the number of deaths averted is increased (Figure 7.10), in this version of the model, removing health-related claims would result in an additional 4141 deaths (95% UI -2220, 9419). Regulating health-related claims using the FSANZ NPSC results in the greatest number of averted deaths (9,450 deaths averted, 95% UI 2468, 18851), regulating with the US FDA model results in 7084 deaths (95% UI -278, 16140) and the EU model results in 6795 (95% UI -203, 15755) deaths.

Figure 7.10 PRIME Results for Models 1-5 when Obesity is and is not taken into account (Sensitivity Model 5)



A sensitivity analyses was also conducted to assess how sensitive the model is to the Odds Ratios for the likelihood of choosing a food when a health-related claim was present (relative to when it is not). For this analyses the ORs were each reduced and increased by 50%, and then using ORs of 1.10 of 1.20 consistently across categories (Table 7.7). Reducing the effect of health-related claims by 50% results in a 43% reduction in the number of additional deaths as estimated by PRIME. Increasing the ORs by 50% leads to 37% increase in the number of deaths. When an OR of 1.10 is applied to all food categories than the number of deaths is reduced by 75%, and setting the ORs 1.20 approximately halves the numbers of additional deaths.

Table 7.7 The sensitivity of the PRIME results to varying the OR for the likelihood of choosing a food when a health-related claim was present (Sensitivity Model 6)

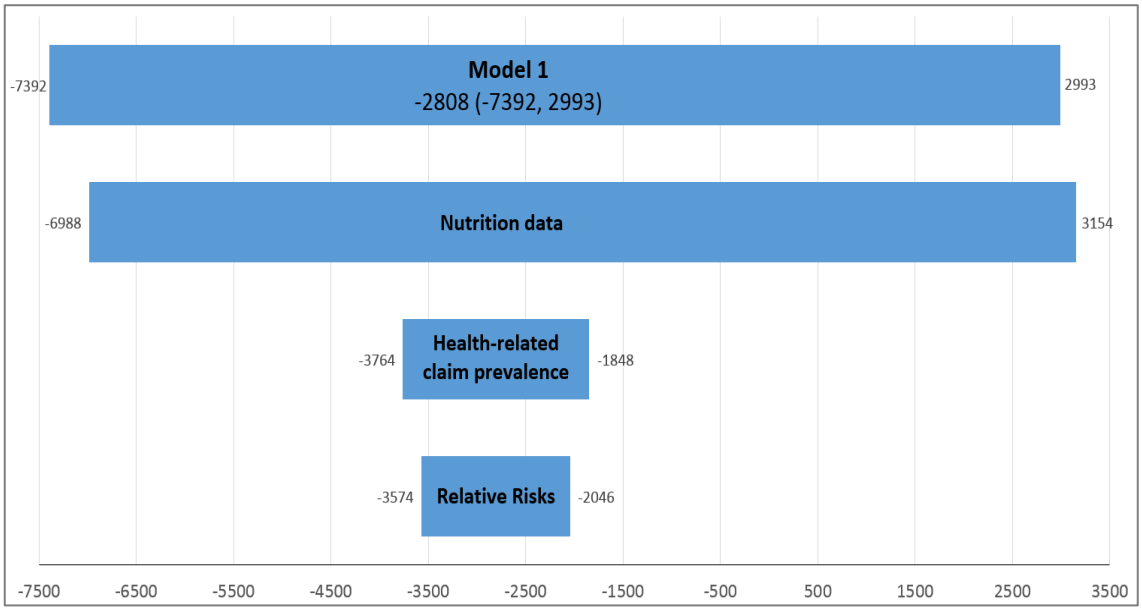
	Model 1	**ORs reduced by 50%**	**ORs increased by 50%**	**OR 1.10**	**OR 1.20**
Applied ORs under each model					
Bread, rice, potatoes, pasta, etc.	1.17	1.09	1.26	1.1	1.2
Composite foods	1.06	1.03	1.09	1.1	1.2
Foods and drinks high in fat and/or sugar	1.35	1.18	1.53	1.1	1.2
Fruit and vegetables	1.92	1.46	2.38	1.1	1.2
Meat, fish, eggs, beans, etc.	2.42	1.71	3.13	1.1	1.2
Milk and dairy foods	1.25	1.13	1.38	1.1	1.2
Excluded/Miscellaneous	1.00	1.00	1.00	1.1	1.2
PRIME results for Model 1 'Heath-related claims removed'					
Total numbers of deaths averted	**-2,808**	**-1,596**	**-3,849**	**-688**	**-1,325**

Uncertainty analyses

The uncertainty intervals were derived from the Monte Carlo analyses (10000 iterations). The intervals are often large and in most instances they cross zero. Under Model 1 the lower interval is -2993 and the upper interval is 7392 a range of 10385. Parameterising the model using analyses conducted at the 'all foods level' slightly reduces the span of the confidence intervals but the range is still large and still crosses zero.

A tornado plot analysis of Model 1 (Figure 7.11) was conducted to assess which parameters contributed the most uncertainty to the model. In Figure 7.11 'Relative risks' refers to the risks associated with the nutrient intake for the dietary risk factors and the health outcomes used by PRIME. 'Prevalence' refers to confidence intervals for the prevalence of health-related claims. These two variables introduce relatively small amounts of uncertainty. Almost all of the uncertainty is due to the data on which the nutrient quality ratios are devised -the variance of the mean level of nutrients of foods that do and do not carry health-related claims as recorded from the food labels. This implies that data extracted on a larger dataset of foods could significantly reduce the uncertainty in the results presented here.

Figure 7.11 Tornado plot for the variance around parameters under Model 1



Discussion

Summary of main findings

When considering the main findings of this chapter, it is important to recognise that the wide uncertainty intervals demonstrate that this dataset is not suitable for making definitive statements about the health outcomes deriving from health-related claims or from different regulation scenarios. As the scenarios that are modelled in this chapter have not been analysed before, the methods that are employed are innovative and the dataset used was the largest example of a representative dataset of foods where health-related claims are identified, the large size of the uncertainty intervals could not have been predicted in advance. Therefore, the large uncertainty intervals are an important finding of this research. The finding that most of the uncertainty in the model was around the food composition data highlights the need for larger surveys of health-related claims. Techniques to develop large food databases are already being employed, for example data mining/scraping nutritional and other information from retailers' and manufacturers' websites, and crowd-sourcing food label data through the use of mobile phone apps (e.g. [189]). However, automated methods for the detection and categorisation of health-related claims on food labels that can be applied to large datasets still need to be developed. One method which could be investigated would be machine learning, but in order for this method to be developed large food training datasets would be required.

Although the results from this chapter should be interpreted with caution due to the large uncertainty intervals, the analyses reveal some unexpected results. Removing health-related claims would result in an additional 2808 deaths (95% UI -2993, 7392) from non-communicable diseases. If we invert this then it follows that health-related claims on food labels currently prevent 2808 deaths. If the FSANZ NPSC model was used to regulate health-related claims (so that only foods that pass the model may carry health-related claims), then

there would be an additional 258 deaths. Greater number of deaths are estimated when the US FDA model was used to restrict health-related claims (-1828, 95% UI -7615 5978) and similarly with the EU model (-1189, 95% UI -7431, 7584). Although further work is needed to reduce the uncertainty around these results, these analyses indicate that regulations of health-related claims – regulations that are currently in place in the US, Australia and New Zealand and recommended for uptake in the EU – might have negative impacts on the nutritional quality of diets, the exact opposite aim of the regulations.

If a nutrient profile model is used to regulate health-related claims but the prevalence of health-related claims is maintained at current levels – reflecting a situation where manufacturers reformulate foods – then a positive health impact is observed for all three nutrient profile models. Under the FSANZ model there would be 4374 (95% UI -2569, 14009) deaths averted. Under the US FDA model there would be 3763 (95% UI -3174, 13225) lives saved, and under the EU model there would be 3151 (95% UI -3783, 12296). In reality, it is likely that some products would be reformulated to maintain health-related claims and some would not. However, the analyses here show that manufacturers' responses to health-related claims (i.e. whether or not they reformulate foods to maintain the prevalence of health-related claims) is an essential input for the assessment of the impact of the regulation of health-related claims. However, there is no clear evidence how manufacturers would respond. Currently there are a small number of studies examining the impact of voluntary health-related logos on reformulation (e.g. [59-61]) but there are no studies that have investigated the impact of health-related claim regulation on reformulation, but such studies are required for an assessment of the potential health impact of the policy.

The results of this study suggest that, in the current situation where foods that carry health-related claims are, on average, healthier than foods that do not carry claims, using a nutrient profile model to restrict health-related claims could have a detrimental effect on health

outcomes. This is due to the fact that reduction in the prevalence of health-related claims outweighs the advantages of improving the nutritional quality of foods that carry health-related claims. In situations where, on average, foods that carry health-related claims are less healthy than foods without claims then using a nutrient profile model is unlikely to have a detrimental effect. There are some known cases where the foods that carry claims are less healthy than the foods that do not [144].

Strengths and limitations of the modelling study

The uncertainty analyses and sensitivity analyses revealed large uncertainty intervals which contain zero. This is likely due to the study being powered to detect a 10% difference in the prevalence of health-related claims – thus underpowered to assess confidently the relatively modest differences in nutrient composition for foods that carry health-related claims and foods that do not, stratified by food group.

One of the assumptions of the 'health-related claims restricted' models (models 2a, 3a, 4a) is that foods that (previously) carried health-related claims but fail the respective nutrient profile model, revert back to nutritional quality of foods that do not carry health-related claims. This is due to how the equations used to disaggregate the LCF data (presented in Figure 7.2 and Figure 7.3) are circular in nature and requires one constant element. This may mean that we underestimate the nutritional quality of foods that do not carry claims, as the nutritional quality of this group may improve with the addition of foods that used to carry health-related claims.

As discussed in Chapter 6, the application of the nutrient profile models does not necessarily reflect how the models are applied in reality. For example, in the modelling described in this chapter the FSANZ NPSC model was applied uniformly to all foods and all types of health-related claim, but in Australia and New Zealand, the model is not applied to foods carrying

nutrition claims and there are additional requisites for many types of health-related claim. Therefore, it is likely that the model is more or less restrictive in reality which may impact the results presented in this chapter.

It is likely that the odds ratios for the likelihood of choosing a food when a health-related claim was present (relative to when it is not) used to parametrise the model over-estimate the effect of health-related claims. Natural experiments examining health-related claims tend to find smaller effects than the ORs from the meta-analyses in Chapter 2. For example, Kiesel (2013, [90]) examined the effect of nutrition claims on snack product sales and found that on average there was a 16% increase in sales for products carrying claims, whereas using the results from the systematic review (Chapter 2) I would estimate a 43% increase. I investigated this with a sensitivity analyses and found that assuming that health-related claims increase purchasing by 20% would half the baseline effect of health-related claims on health outcomes.

One limitation of this modelling study is the combination of data at the European level and at the UK level. I used data from five EU countries to estimate the prevalence of health-related claims and the nutritional differences between products that carry health-related claims and foods that do not. The sensitivity analyses showed that restricting the health-related claim data to products sampled in the UK would vastly increase the uncertainty around the point estimates in the modelling exercise (Sensitivity Model 1, Figure 7.8) but produce point estimates that are broadly similar. I used UK data (the LCF survey, [120]) to estimate the population nutrient intake. The LCF survey is intended to be representative of purchases by the UK population. The average nutrient intake is calculated through combining purchase data with UK nutrient composition data [10] to estimate the average grams purchased per person, per week.

European food databases exist but are often not freely available to use. For example Kantar data [190] contains purchasing data and nutrition data for pre-packaged foods but access to

the data is costly. Euromonitor data [191] is more accessible but has limited nutrition data. Similarly, Mintel's Global New Product Database [192] contains nutrition and sales data and also contains information on health-related food labelling. However, the primary function of the database is to monitor new products available to purchase, therefore it would not be appropriate to use it to estimate the purchases of all foods available on the market.

The modelling exercise is subjected to the limitations of the data which populate the model. The limitations of the health-related claim data are described in the corresponding chapters. The external data used to populate the model also has its limitations. The Living Costs and Food (LCF) survey [120] and the National Diet and Nutrition Survey (NDNS, [10]) data are used to estimate current nutrient intake, however, under-reporting of nutrient intake is a known limitation of most dietary surveys [193]. Under-reporting of food intake may be due to participants forgetting to report food that they have eaten, or the participant may intentionally fail to report details about food that they have consumed. Participants may also be consuming less as they may be intentionally restricting or avoiding foods. Women may be more likely to under-report their food intake, and overweight and obese people are also thought to under-report their food intake [194]. Social desirability bias is thought to occur in surveys when individuals over-report on behaviours that are viewed more favourably and fail to report on less favourable behaviours [195]. The increased public awareness of the negative health outcomes associated with a poor diet may lead to under-reporting [196].

Previous research

Comparisons with the previous literature are difficult as there are no directly comparable studies. However, there are a few studies that examined the impact of individual types of health-related claims. In the main scenario that health-related claims are removed from food labels, it is estimated that the average sodium consumption falls by approximately 100mg. A

systematic review of the effectiveness of salt reduction policies [197] identified a study of the impact of 'low salt' labelling on salt intake. The study found that nutrient labelling interventions could lead to a 480mg (1.2g of salt) reduction of sodium intake. However, this study assumed that 'low salt' labelled products would reflect a 50% reduction in the salt content [198].

A Canadian study modelled the potential impact of traffic light labelling on the nutrient intake of adults by examining food intake data, identifying foods that would score a red light for total fat, saturated fat, salt, and/or total sugars, thus indicating high levels of the nutrient(s), and replacing the food with a similar food which did not have a red light. The study estimated the following reductions in nutrient intake; calories 5%, total fat -13%, saturated fat -14% and sodium -6% [199]. Whereas in this chapter I found the use of health-related claim is associated with smaller changes in calories (-1%), total fat (-3%), saturated fat (-7%) but had a similar finding for sodium (-7%). However, the Canadian study assumes a 100% compliance rate, i.e. all red colour codes were switched for a seminal non-red-light food, which is not a realistic scenario given that much of the previous research has found modest effects of labels on behaviour.

Vyth (2012, [184]) modelled the effect of a health-logo on blood cholesterol levels in the Dutch population. In that study foods that were not eligible to carry the Choices logo were replaced with foods that did meet the nutritional requirements of the program. The effect on blood cholesterol levels was estimated by combining the data on the nutritional differences between the current diet and the modelled diet and meta-analyses of studies concerning the effect of diet on cholesterol levels. From this, Vyth concluded that only moderate effects in blood cholesterol levels would be predicted. However, this study only looked at one health outcome and one type of health-related claim whereas in this thesis I have looked at health-related claims and their effect on mortality from numerous NCDs.

The implications for future research and policy shall be discussed in greater depth in the next chapter (Chapter 8 – Thesis discussion).

8. Discussion

Introduction

In this chapter I summarise the main findings from each chapter and discuss the implications for policy and research.

The aim of this thesis was to measure the prevalence of health-related claims on food labels, evaluate the nutritional quality of foods carrying health-related claims, and to assess whether health-related claims have an impact on population health. The main findings were that health-related claims may have a substantial effect on purchasing/consumption, 26% of foods (95% CI 24%, 28%) of foods carry at least one health-related claim, and that foods that carry health-related claims have, on average, a more favourable nutritional composition than foods that do not carry claims. These findings were synthesised in a modelling exercise with the aim was to estimate the impact of health-related claims on NCD mortality in the UK. The main finding from the modelling study was that larger surveys of the prevalence of health-related claims (with associated nutrient composition data) are required for a thorough health impact assessment of proposed regulation of health-related claims. The results from the modelling study presented in this thesis should be interpreted with caution due to large uncertainty intervals, however the results suggest that health-related claims have a relatively small impact on population health and that the use of a nutrient profile model to restrict claims could have a detrimental effect on population health. However, if manufacturers use nutrient profiling as a target for product reformulation, then there could be considerable benefits to population health.

Main findings from each chapter

The impact of health-related claims on dietary choices (Chapter 2)

There is contention on whether health-related claims could aid consumers in making healthier dietary choices or whether they could hinder them (e.g. through 'health halo' effects). There is also the possibility that they have negligible effects. Experimental studies have mixed findings, some studies found that health-related claims had a strong effect (e.g. that carried out by Wezemael et al [104]), whereas some found that there was little to no effect (e.g. Aschemann-Witzel and Hamm, [79]). I conducted a systematic review of studies of the effects of health-related claims on dietary choices. The primary outcome measure was the likelihood of choosing a product with a health-related claim relative to an identical product without a health-related claim. The secondary outcome measure was the percentage-change in measured purchases or consumption (actual or intended) when a health-related claim was present (relative to when it was not).

Meta-analyses of 17 studies found that products carrying health-related claims were 75% more likely to be purchased or consumed than an identical product without a claim (OR 1.75, 95% CI 1.60, 1.91). The effect size was similar for nutrition claims (OR 1.74, 95% CI 1.29, 2.35) and health claims (OR 1.73, 95% CI 1.57, 1.91). The effect size varied considerably by food group – the effect was greatest for Beans, pulses, fish, eggs, meat and other proteins (OR 2.42, 95% CI 1.87, 3.12) and smallest for studies that examined multiple categories (Dairy and alternatives and Potatoes, bread, rice, pasta or other starchy carbohydrates: OR 1,06 95% CI 0.91, 1.24). Fruits and vegetables with claims were 92% more likely to be purchased or consumed (OR 1.92, 95% CI 1.56, 2.35) and Foods high in fat and/or sugar were 35% more likely (OR 1.35, 95% CI 1.09, 1.66).

The meta-analyses highlighted the need for more research of the impact of health-related claims in real-world settings. The effects of health-related claims are likely to be amplified in

the artificial settings such as choice experiments. Studies that measured consumption and sales in the real world found more modest effects between 6 and 16%.

Whilst the meta-analyses estimates the effect of health-related claims on dietary choices, in order to estimate what, if any, impact health-related claims have on dietary choices we also need to know how much consumers are exposed to health-related claims/how many foods carry health-related claims to estimate their effect on population health.

Prevalence of foods carrying health-related claims (Chapter 4)

Until the studies on the prevalence of health-related claims described in this thesis were carried out it, it was unclear how many foods used health-related claims on their packaging in the EU. A clustered random sampling design was used to collect a sample of foods representative of foods available to purchase in supermarkets and discount stores in the UK, Germany, the Netherlands, Spain and Slovenia. In total, 2034 foods were sampled.

Overall, 26% of foods (95% CI 24%, 28%) carried at least one health-related claim. The UK had the highest prevalence of health-related claims where 35% (95% CI 31%, 40%) of foods carried a health-related claim. Nutrition claims were more prevalent than health claims: (22%, 95% CI 20% 24%, and 11%, 95% CI 10%, 12%, respectively). And, the proportion of foods that carried a health-related claim differed by food group: Dairy and alternatives had the highest proportion – 46% (95% CI 39%, 54%), followed by Fruit and vegetables (33%, 95% CI 26%, 41%), Miscellaneous foods (31%, 95% CI 25%, 36%), and Potatoes, bread, rice, pasta or other starchy carbohydrates (29%, 95% CI 23%, 36%), Foods high in fat and/or sugar (18%, 95% CI 13%, 22%), and Composite foods (16%, 95% CI 11%, 21%).

It has been unclear whether health-related claims are a useful tool to promote a healthy diet. Other researchers have expressed concerns that health-related claims may promote an

unhealthy diet [200]. The results from this study provides mixed support for this. We found that a higher proportion of Fruit and vegetables carry health-related claims than Foods high in fat and/or sugar. But we also found that 46% (95% CI 39%, 54%) of Dairy and dairy alternatives foods carry health-related claims, yet, according to the UK dietary recommendations [72], this food group should make up a small part (less than 10%) of the diet.

In a separate study, using the same sample of foods, combined with estimates from the Global Burden of Disease Study [3] I examined the burden of disease (measured in Disability Adjusted Life Years, DALYs) associated with different diseases within the EU [201]. I found that health claims do not address the biggest causes of ill health and death in each of the five countries we examined, nor the EU overall. For example, whilst 18% of the burden of disease is associated with cardiovascular disease (9% of all DALYs attributable to sub-optimal diets), only 5% of Nutrient and other function claims refer to the heart and/or blood vessel functions. In contrast, 13% of Nutrient and other function claims refer to the digestive system, yet digestive diseases are associated with just 2% of all DALYs [201].

However, health-related claims could still be a useful indicator for healthier foods if foods carrying health-related claims have a more favourable nutritional composition than similar foods that do not carry health-related claims. In this way health-related claims could be used to find healthier alternatives within product categories. To assess whether this is the case I compared the nutritional composition of foods that carry health-related claims to foods that do not carry such claims.

Nutritional quality of foods carrying health-related claims (Chapter 5)

There has been little research on the difference in nutritional quality between pre-packaged foods carrying health-related claims and those that don't. Using the sample of foods used to estimate the prevalence of health-related claims, information for the following nutrients was

recorded from food labels; energy, protein, carbohydrates, total sugars, total fat, saturated fat, fibre, and sodium, per 100g.

The mean levels of the nutrients for foods that carry health-related claims were compared to those of foods that do not carry health-related claims. Foods carrying at least one health-related claim had, on average, significantly lower levels of: energy (-43.7kcal/100g), protein (-1.0g/100g), total sugars (-3.2g/100g), total fat (-4.1g/100g), and saturated fat (-2.9g/100g), and significantly higher levels of fibre (+0.7g/100g).

Nutrient profiling has been defined as 'The science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health' [44]. In the EU, it has been proposed that nutrient profiling should be used to regulate the use of health-related claims. Restricting health-related claims to foods that pass the model currently used in Australia and New Zealand (the FSANZ NPSC) would increase the overall nutritional quality of foods carrying health claims, however it impacts vary between nutrients. For example, there was no significant difference in the mean levels of saturated fat (-2.9g/100g) between foods that carry health-related claims and foods that do no, small differences were seen in regards to protein (-1.6g/100g) and fibre (+1.0g/100g), and large differences for total sugars (-7.3g/100g), sodium (-877.6mg/100g).

Nutrient profile models used for the regulation of health-related claims (Chapter 6)

In Chapter 6 I assessed the strictness of, and agreement between, three nutrient profile models which are used, or haven been proposed for use, for the regulation of health-related claims; the FSANZ NPSC [47], the US FDA model [163], and the model proposed for use in the EU [171]. The three models were similar in terms of strictness – the FSANZ NPSC passes 43% (95% CI 41%, 45%) of foods, the EU model passes 49% (95% CI 47%, 51%), and the US FDA

model passes 39% (95% CI 36%, 41%). In terms of which types of foods should carry claims, there was substantial agreement between the FSANZ NPSC and the EU model (kappa 0.69, standard error 0.02). However, there was weaker agreement between these models and the US FDA (kappa 0.69, standard error 0.02).

The impact of using a nutrient profile model to regulate health-related claims was measured as the percentage of foods that currently carry a health-related claim and pass a nutrient profile model. If the FSANZ NPSC was used to restrict health claims the prevalence would be reduced by 10-points to 16% (95% CI 14%, 18%), under the US FDA model it would be reduced to 23% (95% CI 11%, 14%), and under the EU model it would be 18% (95% CI 16%, 20%).

These findings suggest that, if a nutrient profile model is used to regulate health-related claims, then the choice of model is important. The chapter highlights the need for more validation studies of nutrient profile models as there is no 'gold standard' of which to assess the correctness of the categorisations of nutrient profile models.

The impact of health-related claims on health outcomes in the UK (Chapter 7)

The studies in this thesis have found that health-related claims have a strong impact on choices (Chapter 2), approximately a quarter of foods carry a health-related claim (Chapter 4), and the nutritional composition is only slightly improved in products that carry health-related claims (Chapter 5). If a nutrient profile model is used for the regulation of health-related claims then the choice of model will be important as there is not strong agreement on which types of foods should carry health-related claims. After taking all of this into account, it is unclear whether any of these differences would translate into actual population-level health benefits.

There has been little research on the impact of health-related food labelling on diet and/or on health outcomes, and less on health-related claims. In Chapter 7 I modelled the impact of health-related claims on UK mortality from NCDs. This chapter involved synthesising findings from previous chapters – i.e. the Odds Ratios, prevalence estimates, and nutritional quality information, to estimate the effect of health-related claims on health outcomes.

I developed a front-end model for the Preventable Risk Integrated Model (PRIME, [62]) to assess the effects of different health-related claim scenarios on diets and the associated health outcomes. In this modelling exercise the estimated average nutrient intake is divided into nutrient intake from foods carrying health-related claims and the nutrient intake from foods that do not carry health-related claims. The division of nutrients is scaled according to the odds ratios presented in Chapter 2 and the difference in nutritional quality between foods that carry health-related claims and foods that do not presented in Chapter 5.

The main finding from this chapter was that wide uncertainty intervals demonstrate that this dataset is not suitable for making definitive statements about the health outcomes deriving from health-related claims or from different regulation scenarios. The dataset used for this modelling study was the largest example of a representative dataset of foods where health-related claims are identified therefore the large size of the uncertainty intervals could not have been predicted in advance. An uncertainty analyses found that most of the uncertainty in the model was around the difference in composition between foods with claims and without claims. This highlights the need for larger surveys of health-related claims.

Whilst the results from this study should be interpreted with caution due to the large uncertainty intervals, the analyses reveal some unexpected results. In my modelling study I predict that removing health-related claims from food labels would result in an additional 2808 (95% UI -2993, 7392) deaths. Restricting health-related claims with a nutrient profile model would lead to an increase in mortality. There would be an additional 258 (95% UI -6509,

8706) deaths if the FSANZ NPSC was used, 1189 (95% UI -7431, 7548) if the EU model was used, and 1828 (95% UI -7614, 5978) if the US FDA model was used.

When a nutrient profiling model is used to restrict health-related claims, but the prevalence of health-related claims is maintained at current levels – i.e. assuming manufacturers reformulate foods – then there are gains in population health. Under the FSANZ NPSC model there would be 4374 (95% UI -2569, 14009) deaths averted. Under the US FDA model there would be 3763 (95% UI -3174, 13225) deaths averted, and under the EU model there would be 3151 (95% UI -3783, 12296).

Implications for research

Each chapter in this thesis addresses a gap in the knowledge of health-related claims and identifies areas which need further research. The systematic review (Chapter 2) highlighted the need for more studies on the effect of health-related claims on real world purchases and consumption. Whilst choice experiments give a valuable insight as to how consumers value various product attributes it is not clear how much external validity these experiments have as the experiments are conducted in highly artificial settings and rarely involved participants spending their own money.

The survey of health-related claims (Chapter 4) was the first multiple-country study of health-related claim prevalence since Regulation (EC) 1924/2006 came into effect. The data collection (and extraction) protocols can be used for future studies and the database developed for this study may also serve as a benchmark to measure how the prevalence of health-related claims evolves over time.

Future surveys may benefit by incorporating food groups in the sampling frame. This study found that the prevalence of health-related claims differed by food group, however, the

clustered random sampling design used for the primary data collection for this project did not incorporate food groups into the design, so is underpowered for some types of analyses.

For example, the comparison of the mean levels of nutrients of foods with and without claims (Chapter 4) revealed wide confidence intervals around the mean estimates which was also the main contributor of the wide uncertainty intervals in the modelling study (Chapter 7). However, this was not possible to predict before we conducted this survey. This study would be strengthened if it was supported by greater resources and a larger sample of pre-packaged foods. Furthermore, the survey may underestimate how much consumers are exposed to health-related claims on food labels as the database is not associated with any sales data. Future research could seek to incorporate sales data. Previous research suggests that doing so would result in higher prevalence rates (e.g. [134]).

Implications for policy

This thesis shows that health-related claims can substantially increase purchases and consumption, and health-related claims are prevalent throughout the EU. Health-related claims could potentially have considerable impacts on population health and are therefore a suitable target for regulation. This finding could also be used as justification for funding of future research in this area.

In June 2016 the UK voted to leave the EU and is now expected to formally leave the EU in March 2019. Whilst it is anticipated that most EU laws will continue as UK laws, leaving the EU allows the UK government to amend or remove any EU laws. Due to the large uncertainty intervals associated with the modelling study presented in Chapter 7, one recommendation for the UK government (and/or the European Commission) would be to maintain the current health-related claim legislation whilst commissioning a health impact assessment of the current legislation and the potential impact of using a nutrient profile model. However, even

if such an assessment replicated the results of the modelling study (with smaller uncertainty intervals) it would still be difficult to make a strong assertion on how to improve the current legislation to improve population health. This is due to a lack of understanding in how consumers respond to health-related claims in the real-world, for example consumers may engage in compensatory behaviours such as consuming more foods (rather than substituting foods). Similarly with manufacturers – whilst previous studies suggest that manufacturers are willing to reformulate foods, this is not a certainty, and manufactures could reformulate foods to make them less healthy.

The EC is currently evaluating whether the current legislation is 'fit for purpose' and whether a nutrient profile model is required in order for the legislation to work effectively [46]. The findings in this thesis may be of interest to policy-makers and/or stakeholders involved in that evaluation. The nutritional composition of foods carrying health-related claims is generally more favourable than foods that do not carry claims, so it could be claimed that a nutrient profile model is not required. Furthermore, the results of the modelling study suggest that using a nutrient profile model to restrict health-related claims - and thereby reducing their prevalence – would have detrimental effect on population health. However, if health-related claims and nutrient profiling is used as an incentive to encourage manufacturers to reformulate foods then there could be large population health gains.

This thesis suggests that restricting claims to just the foods with a favourable nutritional composition can have a negative impact on health. However, it could still be damaging if claims were permitted on very unhealthy foods. Therefore an additional policy option could be to use a nutrient profile model to prevent the use of health-related claims on foods with a very poor nutritional composition. In this way nutrient profiling could be used to identify unhealthy foods and restricting their use of claims as opposed to a nutrient profile model being used solely to identify healthier foods and allowing them to carry claims.

Given the finding that health-related claims may increase purchases by up to 75% it is plausible that manufacturers would want to reformulate their foods so that their products would continue to receive that boost in sales. Further research is required in manufacturers' responses to such legislation to be sure of the impact of a nutrient profile model on health. A comprehensive study was conducted by Vyth et al (2010, [61]) who examined manufacturers' responses to the Choices logo. The study found that around half of the products carrying the Choices logo were formulated or reformulated in order to comply with the model. This study involved 47 food manufacturers but only examines their responses to a voluntary logo (The Choices logo). Food manufacturers who already participate in the programme may not be representative of manufacturers who have chosen not to participate.

Another possibility for future research could involve monitoring the prevalence of health-related claims and the nutritional quality of foods over longer periods of time. The sample used in this thesis provides a snapshot of the prevalence and nutritional quality of foods carrying health-related claims. It would be beneficial to repeat the survey at regular intervals to see whether the prevalence or nutritional quality changes over time.

Previous studies have shown that some manufacturers are often keen to reformulate foods so that their foods are eligible to carry certain health logos (e.g. the Choices logo), and also willing to develop new products that meet health logo requirements [60, 61]. And, here in the UK, the food retailer and manufacturer Sainsbury's reformulated foods so that the 'wheel of heath' logo displayed a more favourable nutrient profile [202].

Strengths and limitations of this thesis

The systematic review described in Chapter 2 is the first systematic review that attempts to quantify the effect of health-related claims on dietary choices with a meta-analyses. Some of the planned analyses such as generating Odds Ratios for the effect of health-related claims for

different age groups and by gender were not achieved. This is a limitation that also had an impact on the modelling exercise. As Odds Ratios were not available by age or gender it was assumed that health-related claims affect the population equally – although other systematic reviews suggest that the effect of health-related claims is stronger in young females in higher socio-economic groups [29, 34, 48]. Chapter 2 highlights the lack of studies examining the impact of health-related claims on real purchases.

The methods used to sample foods (to measure the prevalence of health-related claims) were innovative and designed to be easily replicated for future studies. However, it was a time consuming process and its reliability rests heavily upon strict adherence to the protocol. Furthermore, whilst efforts were made to donate the foods purchased, there are ethical issues around the potentially large amounts of food waste such a method generates and the costs of purchasing and storing the foods. As image capture technology improves future research should aim to reduce potential food waste and costs through photographing foods rather than purchasing them. Another potential data collection method is data scraping the nutritional information from retailers' and/or manufacturers' websites. However, more advanced techniques are required for the detection and categorisation of health-related claims. Machine learning could also be utilised to detect health-related claims. However, in order to develop these methods large training databases are required.

The nutritional quality of foods was assessed using the food label data from the prevalence study. Overall, 15% of the foods sampled did not contain any nutritional composition data. The level of provision of nutritional data varied between countries – almost half (47%) of the products sampled in Slovenia did not have any nutritional information compared to the UK where just 8% of foods did not have any nutritional information. This is a limitation as it restricts the number of foods available for the comparison of the mean level of nutrients and increases the reliance on food compositional tables. The missing nutritional composition data

was supplemented with data from the UK Nutrient Databank [119] in order to apply three nutrient profile models. Nutrient profile models were applied to the database to assess the strictness and agreement between models (Chapter 6) and then to estimate the impact of nutrient profiling on health outcomes (Chapter 7).

A limitation of the analyses of nutrition composition data is the use of parametric tests on non-normally distributed data. However, as food category was identified as a potential confounder it was necessary to use parametric analyses that allow for adjusted models (which non-parametric analyses do not). Furthermore, results from the unadjusted parametric tests followed a similar pattern to the non-parametric tests.

Due to the missing nutritional data additional data sources (such as the UK Nutrient Databank) were used to supplement the material. Validity analyses demonstrated that where there were nutritional data on the food labels it was well correlated to the equivalent nutritional data from the UK Nutrient Databank – however, it is not possible to assess how well the missing nutritional data is matched to foods where there isn't any data to compare to. This chapter also shows how it is difficult to apply nutrient profile models in the same manner as they are used in real life. For example, the FSANZ NPSC has a number of additional requisites for specific claims for example, to carry a health claim that refers to the effect of high fruit and vegetable intake on the (reduced) risk of CHD, the product carrying the claim must not be a fruit juice, and must contain at least 90% fruit or vegetable (Schedule 2, [47]). To incorporate these requisites would have required further data collection.

Conclusions

Health-related claims have a substantial effect on dietary choices (OR 1.75, 95% CI 1.60, 1.91). Approximately a quarter of foods throughout the EU carry health-related claims (26%, 95% CI

24%, 28%) and these foods, on average, have a more favourable composition than the foods without health-related claims.

Health-related claims currently have a positive, if modest, impact on NCD mortality. Using a nutrient profile to restrict health-related claims could have a detrimental effect on population health. But, used as a tool for reformulation, a nutrient profile model could vastly increase the impact of health-related claims on NCD mortality. The main finding from the modelling study was that larger data sources are required to reduce the large degree of uncertainty around the results, but that regulation of health claims by nutrient profile models could in some scenarios lead to negative health effects.

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Appendix A Search terms for a systematic review, and meta-analyses, of the impact of health-related claims on dietary choices systematic review (Chapter 2)

Ovid MEDLINE

	Searches
1	(marketing/ or advertising as topic/) and (exp *Food/ or *beverages/ or carbonated beverages/ or energy drinks/)
2	food packaging/ or food labeling/
3	((food* or snack? or fat or fats or sugar? or salt? or sodium or sweet* or soda? or drink? or beverage?) adj5 (label* or pack*)).ti,ab.
4	((nutrition* or nutrient?) adj5 (label* or pack*)).ti,ab.
5	("back of pack*" or "front of pack*" or "on pack*").ti,ab. and (nutrition* or nutrient* or food* or snack* or fat or fats or sugar? or salt? or sodium or sweet* or soda* or drink* or beverage*).mp.
6	(*beverages/ or carbonated beverages/ or energy drinks/ or soda?.ti,ab. or carbonated drink?.ti,ab. or carbonated beverage?.ti,ab. or soft drink?.ti,ab.) and (label* or pack*).ti,ab.
7	(exp Food/ or food?.ti,ab. or snack?.ti,ab. or fat.ti,ab. or fats.ti,ab. or sugar?.ti,ab. or salt?.ti,ab. or sodium.ti,ab. or sweet*.ti,ab.) and (label* or pack*).ti,ab.
8	or/1-7
9	(health-related claim? or logo? or symbol? or tick? or mark? or keyhole?).ti,ab.
10	8 and 9
11	(traffic adj3 light*).ti,ab.
12	((color or colour) adj5 (code? or coding)).ti,ab.
13	11 or 12
14	8 and 13
15	10 or 14

Ovid PsychINFO

	Searches
1	(exp marketing/ or advertising/ or retailing/) and (exp food/ or "beverages (nonalcoholic)"/)
2	exp Labeling/ or product design/
3	exp food/ or food intake/ or diets/ or food preferences/ or nutrition/ or drinking behavior/ or eating behavior/ or health behavior/ or obesity/ or weight control/
4	((food* or snack? or fat or fats or sugar? or salt? or sodium or sweet* or soda? or drink? or beverage?) adj5 (label* or pack*)).ti,ab.
5	((nutrition* or nutrient?) adj5 (label* or pack*)).ti,ab.
6	("back of pack*" or "front of pack*" or "on pack*").ti,ab. and (nutrition* or nutrient* or food* or snack* or fat or fats or sugar? or salt? or sodium or sweet* or soda* or drink* or beverage*).mp.
7	(*beverages/ or carbonated beverages/ or energy drinks/ or soda?.ti,ab. or carbonated drink?.ti,ab. or carbonated beverage?.ti,ab. or soft drink?.ti,ab.) and (label* or pack*).ti,ab.
8	(exp Food/ or food?.ti,ab. or snack?.ti,ab. or fat.ti,ab. or fats.ti,ab. or sugar?.ti,ab. or salt?.ti,ab. or sodium.ti,ab. or sweet*.ti,ab.) and (label* or pack*).ti,ab.
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10	(health-related claim? or logo? or symbol? or tick? or mark? or keyhole?).ti,ab.
11	9 and 10
12	(traffic adj3 light*).ti,ab.
13	((color or colour) adj5 (code? or coding)).ti,ab.
14	12 or 13
15	9 and 14

	Searches
16	11 or 15

OVID CAB Abstracts

	Searches
1	(exp marketing/ or exp food marketing/ or exp advertising/ or exp marketing techniques/ or exp food advertising/ or exp publicity/ or exp sales promotion/) and (exp food products/ or exp food/ or exp foods/ or exp beverages/ or exp lactic beverages/ or exp cocoa beverages/)
2	exp food packaging/ or exp labelling/
3	((food* or snack? or fat or fats or sugar? or sweet* or soda? or carbonated drink? or carbonated beverage? or soft drink?) adj5 (label* or pack*)).ti,ab.
4	((nutrition* or nutrient?) adj5 (label* or pack*)).ti,ab.
5	("back of pack*" or "front of pack*" or "on pack*").ti,ab. and (nutrition* or nutrient* or food* or snack* or fat or fats or sugar? or salt? or sodium or sweet* or soda* or drink* or beverage*).mp.
6	(*beverages/ or carbonated beverages/ or energy drinks/ or soda?.ti,ab. or carbonated drink?.ti,ab. or carbonated beverage?.ti,ab. or soft drink?.ti,ab.) and (label* or pack*).ti,ab.
7	(exp food/ or exp food products/ or exp food groups/ or exp meals/ or exp diet/) and (label* or pack*).ti,ab.
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	(health-related claim? or logo? or symbol? or tick? or mark? or keyhole?).ti,ab.
10	8 and 9
11	(traffic adj3 light*).ti,ab.
12	((color or colour) adj5 (code? or coding)).ti,ab.
13	11 or 12
14	8 and 13
15	10 or 14

Embase

	Searches
1	(exp advertizing/ or exp marketing/ or exp social marketing/) and exp food/
2	exp food packaging/
3	((food* or snack? or fat or fats or sugar? or salt? or sodium or sweet* or soda? or drink? or beverage?) adj5 (label* or pack*)).ti,ab.
4	((nutrition* or nutrient?) adj5 (label* or pack*)).ti,ab.
5	("back of pack*" or "front of pack*" or "on pack*").ti,ab. and (nutrition* or nutrient* or food* or snack* or fat or fats or sugar? or salt? or sodium or sweet* or soda* or drink* or beverage*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
6	(*beverages/ or carbonated beverages/ or energy drinks/ or soda?.ti,ab. or carbonated drink?.ti,ab. or carbonated beverage?.ti,ab. or soft drink?.ti,ab.) and (label* or pack*).ti,ab.
7	(food/ or exp baby food/ or exp beverage/ or exp bran/ or exp cacao/ or exp canned food/ or exp cereal/ or exp chewing gum/ or exp condiment/ or exp cooked food/ or exp dairy product/ or exp dietary fiber/ or exp dough/ or exp edible oil/ or exp egg/ or exp fast food/ or exp fat/ or exp fat substitute/ or exp fermented product/ or exp food color/ or exp food composition/ or exp fruit/ or exp functional food/ or exp genetically modified food/ or exp gluten/ or exp health food/ or exp honey/ or exp margarine/ or exp meat/ or exp nectar/ or exp nut/ or exp organic food/ or exp pasta/ or exp raw food/ or exp roughage/ or exp sea food/ or exp sugar/ or exp vegetable/) and (label* or pack*).ti,ab.
8	1 or 2 or 3 or 4 or 5 or 6 or 7

	Searches
9	(health-related claim? or logo? or symbol? or tick? or mark? or keyhole?).ti,ab.
10	8 and 9
11	(traffic adj3 light*).ti,ab.
12	((color or colour) adj5 (code? or coding)).ti,ab.
13	11 or 12
14	8 and 13
15	10 or 14

Business source complete (EBSCO)

	Searches
1	marketing OR advertising
2	food OR beverages OR drink
3	S1 AND S2
4	food packaging OR food labelling
5	(((food* OR snack? OR fat OR fats OR sugar? OR sweet* OR soda? OR carbonated drink? OR carbonated beverage? OR soft drink?)) AND (label* OR pack*)
6	(nutrition* OR nutrient?) AND (label* or pack*)
7	("back of pack*" OR "front of pack*" OR "on pack*") AND (nutrition* OR nutrient* OR food* OR snack* OR fat OR fats OR sugar? OR salt? OR sodium OR sweet* OR soda* OR drink* OR beverage*)
8	(beverages OR carbonated beverages OR energy drinks OR soda?.OR carbonated drink? OR carbonated beverage? OR soft drink?) AND (label* or pack*)
9	(food OR food products OR food groups OR meals OR diet)) AND (label* OR pack*)
10	S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9
11	(health-related claim? OR logo? OR symbol? OR tick? OR mark? OR keyhole?
12	S10 AND S11
13	traffic AND light
14	(color OR colour) AND (code? or coding)
15	S13 OR S14
16	S10 AND S15
17	S12 OR S16

Web of Science

	Searches
1	**TOPIC:** ((marketing/ or advertising) and (*Food/ or *beverages/ or carbonated beverages/ or energy drinks/)) Indexes=SCI-EXPANDED Timespan=All years
2	**TOPIC:** (food packaging or food labeling) Indexes=SCI-EXPANDED Timespan=All years
3	**TOPIC:** (((food* or snack? or fat or fats or sugar? or salt? or sodium or sweet* or soda? or drink? or beverage?) NEAR/5 (label* or pack*)).) Indexes=SCI-EXPANDED Timespan=All years
4	**TOPIC:** (((nutrition* or nutrient?) NEAR/5 (label* or pack*))) Indexes=SCI-EXPANDED Timespan=All years
5	**TOPIC:** (("back of pack*" or "front of pack*" or "on pack*") and (nutrition* or nutrient* or food* or snack* or fat or fats or sugar? or salt? or sodium or sweet* or soda* or drink* or beverage*)) Indexes=SCI-EXPANDED Timespan=All years

	Searches
6	**TOPIC:** ((*beverages/ or carbonated beverages/ or energy drinks/ or soda?.ti,ab. or carbonated drink?.ti,ab. or carbonated beverage?.ti,ab. or soft drink?) and (label* or pack*)) Indexes=SCI-EXPANDED Timespan=All years
7	**TOPIC:** ((Food/ or food? or snack? or fat or fats or sugar? or salt? or sodium or sweet*) and (label* or pack*)) Indexes=SCI-EXPANDED Timespan=All years
8	#7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1 Indexes=SCI-EXPANDED Timespan=All years
9	**TOPIC:** ((health-related claim? or logo? or symbol? or tick? or mark? or keyhole?)) Indexes=SCI-EXPANDED Timespan=All years
10	#9 AND #8 Indexes=SCI-EXPANDED Timespan=All years
11	**TOPIC:** (("traffic" NEAR/3 "light*")) Indexes=SCI-EXPANDED Timespan=All years
12	**TOPIC:** (((color or colour) NEAR/5 (code? or coding))) Indexes=SCI-EXPANDED Timespan=All years
13	#12 OR #11 Indexes=SCI-EXPANDED Timespan=All years
14	#13 AND #8 Indexes=SCI-EXPANDED Timespan=All years
15	#14 OR #10 Indexes=SCI-EXPANDED Timespan=All years

Appendix B Review Risk of Bias table for a systematic review, and meta-analyses, of the impact of health-related claims on dietary choices systematic review (Chapter 2)

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
Ares (2008)	Randomly recruited in public areas (shopping areas, universities etc.).	NA - choice order was randomised.	NA.	Unclear.	Unclear.	Unclear - reported nutritional knowledge slightly lower than reported in some European studies.	Sensory Science Scholarship Fund. GlaxoSmithKline Consumer healthcare for the Rose Marie Pangborn Sensory Science Scholarship.	No conflict of interest statement.
Ares (2009)	Randomly recruited in public areas (shopping areas, universities etc.).	NA - choice set was not randomised to reduce contamination.	Unclear.	Unclear.	Unclear.	Unclear.	Sensory Science Scholarship Fund. GlaxoSmithKline Consumer healthcare for the Rose Marie Pangborn Sensory Science Scholarship.	No conflict of interest statement.
Ares (2010)	Randomly recruited in public areas	NA - all participants completed the	NA.	Unclear.	Unclear.	Yes.	Sensory Science Scholarship Fund.	No conflict of interest statement.

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
	(shopping areas, universities etc.).	same 18 choice sets.					GlaxoSmithKline Consumer healthcare for the Rose Marie Pangborn Sensory Science Scholarship.	
Ascheman n-Witzel (2010)	Unclear.	NA.	NA.	Unclear.	Unclear.	Mixed - age and gender quota sampling but persons with a higher education level were over-represented.	The empirical research was funded by the German Research Foundation (DFG).	No conflict of interest statement.
Ascheman n-Witzel (2013)	Randomly recruited in public areas (shopping areas, universities etc.).	Yes - claim set rotated equally between participants.	NA.	Unclear - asked to choose one brand.	Yes - told they will be asked to choose (or not) a product.	Yes - age and gender quota sampling	German Federal Ministry of Food, Agriculture and Consumer Protection in the frame of the federal funding scheme for organic agriculture (BÖL, FKZ: 06OE120).	No conflict of interest statement.
Barreiro-Hurle (2010)	Randomly recruited in public areas (shopping areas,	NA - 80 choice sets randomly split into 20 blocks, each	NA.	Unclear.	Unclear.	Yes - stratified random sampling by town and age.	DISOPTIPOL project funded by INIA-MICINN and EU FEDER	No conflict of interest statement.

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
	universities etc.).	participant one block of four choice sets.				Town socio-demographics representative of the Spanish Census of Population (INE, 2004).	through research grant RTA2005-0020. JBH undertook this research while contracted under the INIA-CCAA cooperative research system post-doctoral incorporation scheme, partly funded by EU-ESF.	
Belei (2012)	Unclear.	Yes.	Unclear.	Unclear.	Unclear.	Unclear.	European Union (Marie Curie Individual Fellowship Grant 254931), Netherlands Organization for Scientific Research (Veni Individual Grant 451- 10-009), and Marketing Science Institute (Grant 4-1743).	No conflict of interest statement.
Carbonnea	Various	Yes.	Unclear.	Yes - told that	Mixed - asked to	Unclear.	Canadian	Authors state

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
u (2015)	advertisements (e.g. flyers, forum postings, email, etc.).			this study aimed to rate the appreciation of a new 7 day menu over a 10 day period.	return uneaten food but not told it would be weighed.		Institutes of Health Research (CIHR) (grant no. MOP-110951).	that there are no conflicts of interest.
Casini (2014)	Recruited in-person.	NA - 16 choice situations divided into two blocks of eight sets.	NA.	Unclear.	Unclear.	No.	Unclear.	No conflict of interest statement.
Coleman (2014)	Research panel	NA - same choice set.	NA.	Unclear.	Unclear.	Unclear.	Unclear.	Authors state that there are no conflicts of interest.
Contini (2015)	Unclear.	NA - 64 choice pairs divided into 4 blocks of 16 sets.	NA.	Unclear.	Unclear.	Yes - sample representative for age, gender, and education (and consumers of olive oil).	Unclear.	No conflict of interest statement.
De Marchi (2016)	Research panel	NA.	NA	No - cheap talk script.	Yes - cheap talk script.	Unclear.	Tyson Chair Endowment at the University of Arkansas, by the National Research Foundation of Korea (Grant	No conflict of interest statement

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
							NRF-2014S1A3A2044459) and by the Research Council of Norway (Grant-233800)	
De-Magistris (2016)	External agency	NA	NA	No – informed consent.	Yes – informed consent.	Yes - random stratified sampling according to gender, age, and BMI.	European Commission FP7-MC-CIG-332 769, Fighting against obesity in Europe: the role of health-related claim in food products (OBESCLAIM).	Authors state that there are no conflicts of interest.
Fernández-Polanco (2013)	Randomly recruited in public areas (shopping areas, universities etc.).	NA - choice order was randomised.	NA.	Mixed - told that investigating consumer preferences for fish.	Mixed - told that investigating consumer preferences for fish.	Yes.	Unclear – "The authors wish to acknowledge the following persons and institutions: the board and members of the ''Mercado de la Esperanza'' (Santander, Spain) retailers' association for	No conflict of interest statement.

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
							their inestimable cooperation and support in the field work of this and other researches."	
Gracia (2009)	Unclear.	NA - choice order was randomised.	NA.	Unclear.	Unclear.	Yes - stratified random sampling design based on town and age.	Unclear.	No conflict of interest statement.
Kiesel (2013)	Unclear - authors were not given information on how stores were selected.	NA.	NA.	NA.	NA.	Authors were not given information on how the five stores were selected.	Giannini Foundation.	No conflict of interest statement.
Koenigstorfer (2013)	Recruited in university hallway.	Unclear.	Unclear.	Yes.	No.	Unclear - University students.	Postdoc-Programme of the German Academic Exchange Service (DAAD).	No conflict of interest statement.
Kozup (2003)	Research panel	Unclear.	Unclear.	Unclear.	Unclear.	Unclear.	Unclear if University funded.	No conflict of interest statement.
Krystallis (2012)	Research panel	NA - choice order was randomised.	NA.	Unclear.	Unclear.	Unclear.	Unclear.	No conflict of interest statement.

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
Lin (2015)	Convenience sampling.	Yes.	Unclear.	Unclear.	Unclear.	Unclear.	Unclear.	No conflict of interest statement.
Loose (2013)	Research panel	NA - choice order was randomised.	NA.	Unclear - asked about oyster preference.	Unclear - asked about oyster preference.	Maybe - females and older participants slightly over-represented compared to other seafood research (Olsen, 2003).	Australia's Fisheries Research and Development Cooperation (FRDC).	No conflict of interest statement.
Maubach (2014)	Research panel	NA - choice order was randomised.	NA.	No - informed consent.	Unclear.	Unclear.	Department of Marketing at the University of Otago.	Authors state that there are no conflicts of interest.
McLean (2012)	Research panel	NA - choice order was randomised.	NA.	Unclear.	Unclear.	Random selection from national research panel 50% with/without hypertension.	Health Research Council of New Zealand through the University of Otago.	Authors state that there are no conflicts of interest.
Mohebalian (2012)	Research panel	NA.	NA.	Unclear.	Unclear.	Yes - participant data fit well with census data.	Unclear.	No conflict of interest statement.
Mohebalian (2013)	Research panel	NA.	NA.	Unclear.	Unclear.	Yes - participant data fit well with census data.	Partial funding: Sustainable Agriculture Research and	No conflict of interest statement.

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
							Education (SARE) grant, LNC10-324.	
Moon (2011)	Research panel	Yes.	Unclear.	Unclear.	Unclear.	Yes.	Illinois Missouri Biotechnology Alliances (IMBA).	No conflict of interest statement.
Orquin (2015)	Research panel	Studies 1-3: Yes.	Unclear.	Yes - All experiments had cover stories to minimize demand characteristics.	Unclear.	Unclear.	Partial funding: Danish Council for Strategy Research (grant 2101-09-044- "Bridging the gap between health motivation and food choice behaviour: A cognitive approach" (HEALTHCOG)).	No conflict of interest statement.
Roberto (2012)	Various advertisements (e.g. flyers, forum postings, email, etc.).	Yes - stratified by gender.	Unclear.	Unclear - told they would be asked to taste a cereal and provide feedback.	No- asked filler questions about other aspects of the cereal. 27 participants excluded as correctly identified study was testing influence of	Unclear.	Rudd Foundation and Robert Wood Johnson Foundation.	Authors state that there are no conflicts of interest.

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
					nutrition information.			
Steenhuis (2010)	Various advertisements (e.g. flyers, forum postings, email, etc.).	NA - choice order was randomised.	Unclear.	Yes - experiment was presented as a product evaluation study.	No - true purpose of the experiment was not revealed to the respondents until the entire experiment was finished.	Unclear.	Unclear.	No conflict of interest statement.
Van Wezemael (2014)	Research panel.	Yes.	Unclear.	Unclear.	Yes - participants told about the attributes that were included in the study.	Yes - representative for each of the national populations in terms of gender and age.	EU FP6 Integrated Project ProSafeBeef, Contract No. FOOD-CT-2006-36241 and the Agricultural University of Athens.	No conflict of interest statement.
Wansink (2006)	Recruited at a University.	Study 1: No. Study 3: Unclear.	Unclear.	Study 1: Mixed - participants asked if they wanted to be involved in a series of demonstrations and short surveys about	Study 1: Unclear. Study 3: No.	Study 1: Unclear. Study 3: Unclear.	Funding source not given but authors declare that "No industry or government agency funds sponsored this project."	No conflict of interest statement.

First author (year)	How were participants recruited?	Were participants randomised to claim condition? Y/N	Were participants aware of claim allocation? Y/N	Were participants blind to study aims? Y/N	Were participants aware of study outcomes? Y/N	Were participants representative of the target population?	How was the study funded?	Any conflict of interests declared?
				how consumers make choices and decisions. Study 3: Yes - participants asked to evaluate a pilot episode for a television show.				

Appendix C Protocol for CLYMBOL Research protocol task 1.3: Prevalence of health claims, health symbols and their context

Note: This protocol was circulated to all task partners involved in the data collection for the CLYMBOL project.

Task leader: EUFIC (partners involved: University of Ljubljana, University of Surrey, University of Oxford, Saarland University, Agrifood Research and Technology Centre of Aragon)

Objectives: To provide a benchmark of the prevalence and consumer exposure to health claims and symbols and the context they appear in.

Description of task: This task will provide detailed information on (types of) health claims/symbols and their context for various product categories, a basic starting point for studying the role of health-related symbols and claims in consumer behaviour. Data collected as part of the EC-funded FP7 project FLABEL on penetration of nutrition and health-related information on food packages in the EU 27 countries and Turkey will serve as a point of departure. These data will be supplemented by new data in 5 selected countries, in 3 stores each (covering different retail formats in one city). Data collection will track the taxonomy of health claims, health symbols and their context as established in Task 1.2. Country differences in the history of use of health claims and health symbols (established in Task 1.1) will be considered in the selection of studied countries.

In addition to allowing an analysis of penetration of claims and symbols, new data will be subjected to an analysis of the context in which health claims and symbols appear on the food label, with the aim of establishing a typology of context elements that can have a potential impact on claim and symbol understanding and their effect on purchasing and consumption.

Deliverable 1.3: A database of health claims on the market

<u>The protocol contains:</u>

1) Detailed information on the setup of the study, defining study subject, sample population, and claims. An overview of store (and city) selection, justification and sampling procedures will be given, including:
    a. A data sampling and collection protocol, to guide researchers on which products to select for this study
    b. An Excel file for generating randomised numbers off store lists and floor plans ("Randomisation for CLYMBOL.xlsx")
    c. A data extraction protocol, to guide researchers on how to note down the information and data needed from the products purchased, including an excel file for data entry ("Data extraction_product sampling CLYMBOL WP1 task 1.3") and a data key ("Data extraction workbook guidance CLYMBOL.docx")

2) A data sheet (.xls) containing all selected categories of data and information that shall be collected in this study. This Excel file will be used by partners in the five EU countries (UK, SP, DE, SI and NL) where data collection will take place.
    - ➔ In addition to the Excel grid, a list of all accepted health claims in bilingual translation (EN to other language) will be provided to help identify the English equivalent to the national health claim found on a product
    - ➔ Further, a template store permission letter has been created for those countries where store permissions need to be sought after
3) An appendix on the food categories used in this data collection and extraction process, based on Dunford et al. (2012).
4) An appendix on claim definitions, categorisations and types of claims, based on the EU Health Claims Regulation 2006 and the taxonomy developed for CLYMBOL in task 1.2.

Aims of the study

The products sampled will be used to determine the prevalence of symbolic and non-symbolic nutrition and health claims and other symbolic labelling within different stores in different (European) countries. Data from these surveys will also be used to assess the nutritional quality of foods carrying certain forms of labelling.

1) What proportion of pre-packaged foods available in-store in the five countries carry health (and nutrition) claims?
2) What proportion of pre-packaged foods available in-store in the five countries carry health symbols?
3) Which health claims and symbols can be found on the pre-packaged food and drink products?
4) Which product categories have the highest prevalence of health claims and/or symbols?
    a. Do the five countries differ in their prevalence of health claims and symbols available on products?
    b. Do the different types of stores in the five countries differ in their prevalence of health claims and symbols available on products?

Protocol

Foods are sampled from pre-packaged products sold in three different types of stores, in five EU countries. Countries were chosen on the basis of project requirements as well as a geographical spread and expected differences in the prevalence of health claims and symbols. The types of stores were selected with the aim to cover a range of different outlets, and to ensure a realistic picture of the prevalence of health claims and symbols, as available to consumers in the five countries.

Countries

- UK (partner: UniS, support by UOXF)
- Netherlands (partner: EUFIC, subcontracted work at University Wageningen)
- Germany (partner: UdS)
- Slovenia (partner: UL)

- Spain (partner: CITA)

Selection of stores

1) **Large supermarket / national retailer:** a store (close to the location of the partner in charge) of the chain with high national market share. Additional characteristics include a comparable size (square metres) and similar day/time of data collection across the five countries.
2) **Discounter:** a store (close to the location of the partner in charge) of the discounter with high national market share. Additional characteristics include a limited range of products, a high proportion of private labels within the assortment and limited service (often: self-service) in-store. As per definition, selling space of a discounter must not exceed 1,000 m^2. Day and time of data collection must be comparable across the five countries.
3) **Neighbourhood store:** a store (close to the location of the partner in charge) with a sales area of 400 – 1,500 m^2 and a product range of 7,000 – 12,000 items. The percentage of non-food items must not exceed 25%. Additional characteristics include a high national prevalence of the chain selected and similar day/time of data collection across the five countries.

Overview of stores per country

	UK	Netherlands	Germany	Slovenia	Spain
Large Supermarket / national retailer	Tesco	Albert Heijn	Kaufland (GLOBUS)	Mercator Megamarket	Mercadona
Discounter	Lidl	Aldi	Aldi	Hofer/Lidl	DIA
Neighbourhood Store	The Co-operative Food	Spar	Edeka Active	Spar Market	Sabeco

Subcontracting budget

EUFIC	UniS	UdS	UL	CITA
4,000 EUR	1,500 EUR	1,500 EUR	4,000 EUR	1,500 EUR

Budget is available to subcontract field workers who will visit the stores to buy products off a list. If purchased by the partners themselves, EUFIC as coordinator can change the type of cost and transfer the corresponding amount to ODC. If necessary, budget can also be transferred between the partners to ensure the purchase of the selected products.

Defining the population of pre-packaged foods

A food is defined as any single food or drink item available for sale in the stores selected for this study. This definition allows the same food in different sized packages to be included in

the survey, on the basis that the packaging for the same food in different sized packages may carry different nutrition/health claims.

Only pre-packaged foods are considered and not unpackaged foods. The EU Food Labelling Directive defines a 'pre-packaged foodstuff' as 'any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging.'

All Seasonal/festivity related products which meet the criteria above will be eligible for random selection.

Exclusion of products will occur pre and post sampling. Pre-sampling exclusion will occur for categories that have a low or no proportion of (eligible) foods. This includes promotional stands which tend to mix food and non-food items, often offer unpackaged, lose food and/or duplicate food elsewhere available. Post-sampling exclusion will occur for products selected in the (eligible) food categories that are ineligible, e.g., fresh food counters, loose products, deli etc.

Products which are excluded from this study:

- Non-food items, i.e. items included in appropriate food categories but which are not foods, e.g. birthday candles under 'Food Cupboard/Baking'
- All 'unpackaged' foods that can be identified as such

All items within the chosen food categorisation scheme, excluding

- Alcoholic drinks (including low alcohol drinks)
- Supplements (excluded from all CLYMBOL research)
- Deli-style products and all additional products within the 'Fresh Food/Counters' category, as the overwhelming majority of products is sold unpackaged; a very small minority of eligible products within this category will thereby be excluded. This is a compromise on grounds of sampling practicality where the inclusion of a category rather than individual products will assist the product ID numbering procedure

Sampling and data collection

The present study will apply a two-step approach when sampling the food and drink products used to analyse the prevalence of health/nutrition claims and symbols. In a first step, randomised sampling of a fixed amount of foods will be used to ensure a realistic picture of foods available in a given store, in a given city, at a given point in time. This data shall be roughly comparable across all five EU countries chosen for this study. Based on the data obtained from the randomised sample, a second, purposive sample will be drawn from the large supermarket/national retailer selected in each country. The objective of this second sample is to complete the picture of health claims and symbols available, for two specific product categories. These categories will be selected based on the preliminary analysis of the first set of data: highest percentage of health claims and symbols in one product category and highest variety of health claims and symbols within one product category.

1) Randomised number generation (in-store)

This sampling method requires either a store/stock list or a floor plan of the store. In all five countries, partners will try to obtain such store/stock lists and only apply the store floor plan method when no lists are available.

a) Using the **store/stock list**, randomised numbers will be generated using the Excel file ("Randomisation for CLYMBOL.xlsx") provided. A set of 300 numbers will be generated in order to have back-up for duplicates the calculation may produce or for products that cannot be obtained in the store. This procedure will be repeated for all three types of store.

   The retailer may provide the store/stock lists in a variety of different formats (e.g. an Excel spread sheet, a PDF list, or a printed copy of a list). The products on the store/stock lists should be grouped (or sorted) by the retailer's own food categories. Researchers should use the criteria outlined in page 4 to exclude the relevant categories (e.g. non-food items, supplements and alcoholic drinks), then assign the remaining categories an ID number and count the number of products per eligible category. These values should then be entered in the "Randomisation for CLYMBOL" Excel file.

   To use the excel sheet, the number of products for each category should be entered by the researchers (in column B). The randomised section and product numbers will then be displayed in columns G and H. The spread sheet is designed for a maximum of 100 categories – should there be more categories, please contact UOXF who will amend the spread sheet accordingly. If there are fewer than 100 categories then a value of '0' should be entered for any unused/extra categories. The spread sheet uses Excel's RAND function to generate random numbers, this function will generate new numbers each time that the spread sheet changes (e.g. by entering in new values). Therefore, once the researcher has generated the randomly selected foods, they should copy columns G and H and then use the 'paste values' function to paste their random selection elsewhere, in order to preserve it.

   As with the store/stock list method, randomised numbers will be generated using the Excel file "Randomisation for CLYMBOL.xlsx". Duplicates are not an issue with this approach. Researchers are asked to record any instances where products generated via the Excel file could not be obtained in-store. All lists with the randomly generated products shall be sent to the task leader (EUFIC), after finishing the data collection. This Excel file can contain an additional spread sheet with this information.

   Additionally, in order to check for the quality of any obtained store/stock lists, a fixed number of additional products (10% of the total sample of products -> 10% in the supermarket, the discounter and the neighbourhood store each) will be randomly purchased in-store and then checked against the store/stock list provided by the store. This procedure is to ensure that the store/stock lists are accurate and do not account for a distortion of the randomised product sampling.

b) Only when store/stock lists are not available, a **floor plan** will be created in-store. The floor plan needs to describe the layout of the store and include a brief description of the food

products in each aisle. It should also include the locations of promotional stands or other non-aisle displays. Once a floor plan has been created, each section/aisle needs to be assigned a number. The researcher must then make an estimate of how many products are available in each section. To do this with more accuracy, one side of an aisle will be counted, preferably using a tally counter, and the remaining section estimates will be based on this number. Sections that significantly differ to the aisle, e.g. promotional displays, circular stands etc., will also be counted in order to make the estimates for the number of products in these sections more accurate.

As the inclusion criteria above state, different sized/packaged variations of the same product will be considered as different products (e.g. a 500ml bottle of cola and a 330ml can of cola). As aisles may appear to contain fewer unique products it will be important to check whether the product is packaged differently. Similarly, some products will be allocated more shelf space than others due to the size of the packaging, thus when picking an aisle to count the products, researchers should try to pick an aisle that they feel is representative of most food or drink packaging or that has a variety of food packaging sizes.

Smaller stores such as neighbourhood or local stores may have a less homogenous layout compared to larger stores. This may make estimating the number of products per section more difficult. If feasible, researchers are asked to count the number of unique products in each section using a tally counter.

The researcher needs the following information for the in-store sampling:

- A store floor map with each section assigned an ID number (see attached diagrams)
- An estimate of the number of products per section
- An estimate of the total number of products

Once the section and product number have been selected, the researcher can use the floor map to find the corresponding product. For example, the section ID that has been selected is '2' and the product ID selected is '192': the researcher will use the floor plan and tally counter to count along to the 192nd product in section '2'. The random numbers generated should be sorted by section and then by product selection so that products can be selected from one section at a time. If duplicated products are selected (as the same product may be in different sections of the store) researchers should proceed with a new randomly chosen section and product number. Researchers are asked to keep a record of the number of duplicated products they selected along with notes of any issues that arose during the task. As mentioned above, all lists of randomly generated products will be sent to the task leader (EUFIC) after completing the data collection. Additional info on duplicates etc. can be inputted in this list. The attached diagrams suggest the directions that products should be counted in, making the method more systematic.

c) 400 products will be **purchased** in each country, of which
   - 250 will be sampled in the supermarket/national retailer and
   - 75 in the discounter and the neighbourhood store each

When sampling 400 foods in each country, a prevalence estimate of +/- 5% (approximately) can be reached, meaning 400 foods would be enough to distinguish a 10% point difference (of health claims) between countries.

To enable close examination of the packaging of each product, all products are sought for purchase from the store. Products are selected and purchased in the same time frame (1 month) for all countries. Once the foods have been purchased, the packaging will be removed from the product and assigned an ID number for the purposes of data management.

In order to reduce any inconvenience to the store owners or other shoppers, researchers are asked to follow the advice below:

- Researchers should inform supermarkets of the purpose of their visit
- Please discuss the visit times with the store-owners to avoid peak periods and try to visit soon after stock has been replenished on shelves.
- When visiting the store, researchers should avoid causing any disruption to shoppers.
- If the estimated number of products is higher than the actual number of products in a section, there is a possibility that the random number selected will not represent an actual product in that section (for example if the 156th product is selected from a section with 150 products). In these instances, a new section and product number should be selected.

2) Purposive sampling

In addition to a randomised sample as described under 1), a second step will involve a purposive sampling of products, with the goal of completing the range of product categories containing most or the highest variety of claims. These will be selected based on the food categorisation scheme in Appendix 1. This procedure aims at offering a more complete view on foods available bearing health claims and symbols. They will be selected upon analysis of the random sample and will be chosen in order to account for

a. the category with the highest percentage of health claims and symbols
b. the category with the highest variation of health claims and symbols

A specific protocol will be developed for the purposive sampling, based on results from the first data collection phase and analysis. Depending on the results of the first phase of data collection (randomised sampling), several options are available: 1) both categories are the same for all countries versus 2) one category will be chosen cross-country and one category will be chosen independently in each country, using one of the two options above (a and b). Alternatively, a set of products will be chosen based on other criteria which may emerge from analysing the random product sample.

Once the product categories are selected, shoppers will return to the same stores and purchase the remaining products within each product category.
Note: To minimise environmental impact, the product disposal process will involve packaging removal, basic product repackaging (using bags and boxes), and offering these products to colleagues by email invitation. Donations will be offered for local charities assisting homeless people or any other consumer group with low access to food.

Data extraction

An accompanying Excel data spread sheet has been designed to store all information derived from the purchased products' packaging, including food composition data, price and labelling information (nutrition and health claims). The food categorisation scheme in Appendix 1 will be used to classify each product and ensure comparability across the countries. Appendix 2 gives a detailed explanation of the taxonomy and the understanding and classification of each type of claim within the project CLYMBOL.

1) Data is collected on:

- **Pictures:** front, back, both sides and if necessary from the top. **Only of products containing claims and/or symbols.**
- **Information:** see list below

Type of information	Specification
Product information	Country
	Store type
	Product code (internal number, including a country code)
	Product name (name, brand name, manufacturer)
	Food category (Dunford et al. 2012)
	Price per pack
	Nutritional information provided (Y/N)
	Nutrient specific systems (e.g., traffic light labelling of nutrients)
	Nutrient specific system position (FOP, Not FOP, FOP+other)
	Summary indicator systems (e.g., 1-100 healthiness ratings) (Y/N)
	Further details of summary indicator systems
	List of ingredients (Y/N)
	Product information claims that appear on packaging:
	Dairy/Lactose free (Y/N) – *this can be worded or symbolic* Wheat/gluten free (Y/N) – *this can be worded or symbolic*
	Vegetarian (Y/N) – *this can be worded or symbolic*
	"no artificial preservatives" (Y/N)
	"no artificial colours" (Y/N)

Type of information	Specification
	"no artificial flavours" (Y/N)
	Other (please specify)
Manufacturer-provided nutritional information (in grams per 100grams unless specified otherwise)	Recommended serving size (grams)
	Energy (KJ per 100g)
	Energy (kcal/100g)
	Protein Carbohydrate
	Total sugars
	Total fat
	Saturated fat
	Fibre
	Sodium (mg/100g)
Additional information required for nutrient profiling	% fruit and vegetables
	% meat % dairy constituents
	% of cereals
	% bread, cereal, rice, pasta
	% soy protein
Nutrient profile model food groups	EU model 2009
	FSANZ
	Keyhole
	Choices
	Finnish Heart
	US FDA Requirements for foods carrying a health claim
Claim characteristics **Anything that resembles a claim should be noted down. The same goes for symbols!**	Claim codes (one code for all claims found on each product and one code assigned by EU register for health claims)
	Claim description (verbatim in original language and translated into English)
	Number of times the same claim appears on packaging
	Position (FOP, Not FOP, FOP+other)
	Worded, symbolic or both
	If symbolic, please specify name of health symbol

Type of information	Specification
	Target population (if specified)
	If other please specify
	Nutrient (if specific)
	If other substance/ingredient please specify
Claim type	
- **Nutrition claim**	Health-related ingredient claim
	Nutrient content claim
	Nutrient comparison claim
- **Health claim**	General health claim
	Nutrient and other function claim
	Reduction of disease risk claim
	Children's development and health claim
	Effect Direction
	Effect certainty
	Framing
	Disease and health state
Comments	

The current list of EFSA approved health claims (n=222 for functions/weight control and n=21 for disease risk and children) is available in bilingual translation (EN to other language) here and will be used to assign internal identification codes to each health claim. An Excel document containing all translations has been prepared and shared with the partners. This will reduce the time spent on translating the verbatim health claims into English for analysis purposes.

2) Duplicates

For cross-country comparison: duplicates will remain as the information will be needed for task 2.2, analysing indicators for nutritional and health status.

For within-country (across stores, per country) **comparison:** duplicates can remain in the analysis as the stores are compared against each other, for prevalence and incidence of claims and symbols.

Different product sizes and flavours of the same brand will count as different products, not duplicates.

3) Inter-coder variability (across-country)

Each partner will send a copy of the data entry Excel file to the task leader (EUFIC) as soon as the first 10 products have been coded. EUFIC and UOXF will check the data extraction and verify that all data points have been entered correctly. Should any discrepancies appear, EUFIC will contact the respective partner/researcher and corrections/additional trainings will be undertaken.

4) Inter-coder variability (within-country)

A sample of products (5%) from each store will be re-coded by another coder. Pictures shall be checked for quality and readability. This may be done by a local coder or alternatively sent to EUFIC and/or UOXF to check.

Differences in the data extraction between coders are then assessed qualitatively: all data collected from each coder is scanned to assess particular difficulties with the understanding, correct classification and noting down of the required product information, spelling (of claims), and quality of pictures taken.

Diagram 1: Store plan

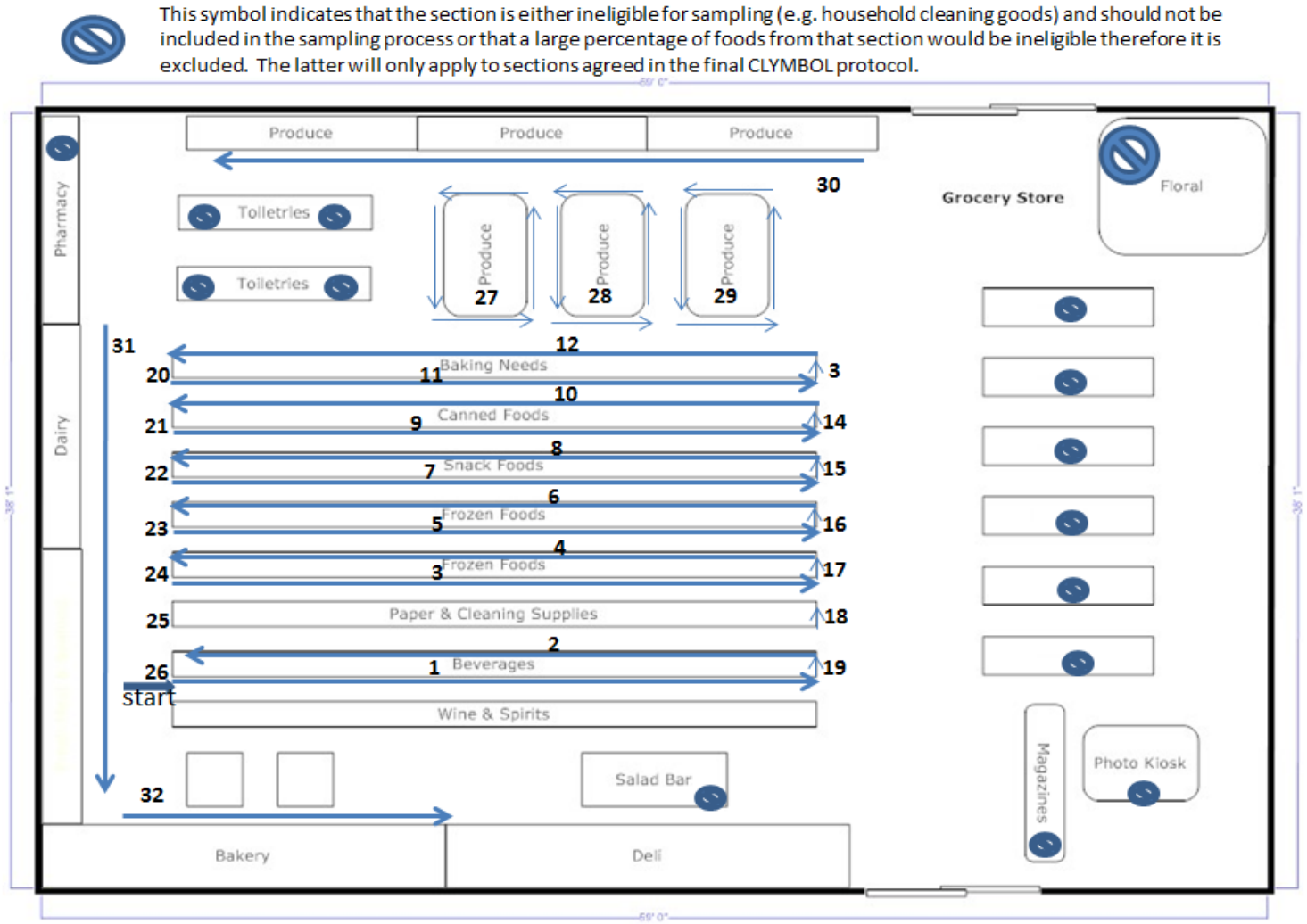
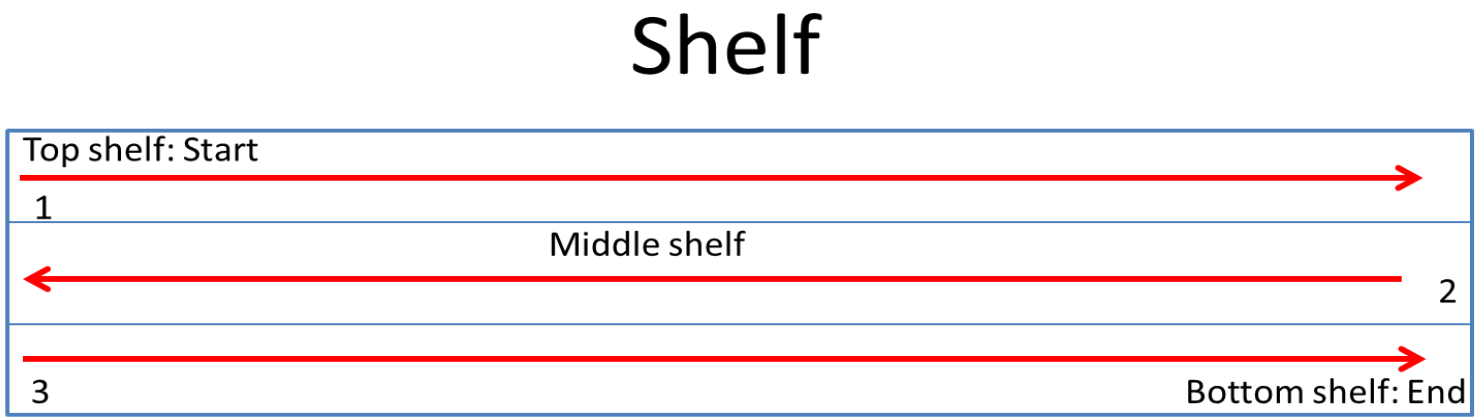


Diagram 2: Direction of product count



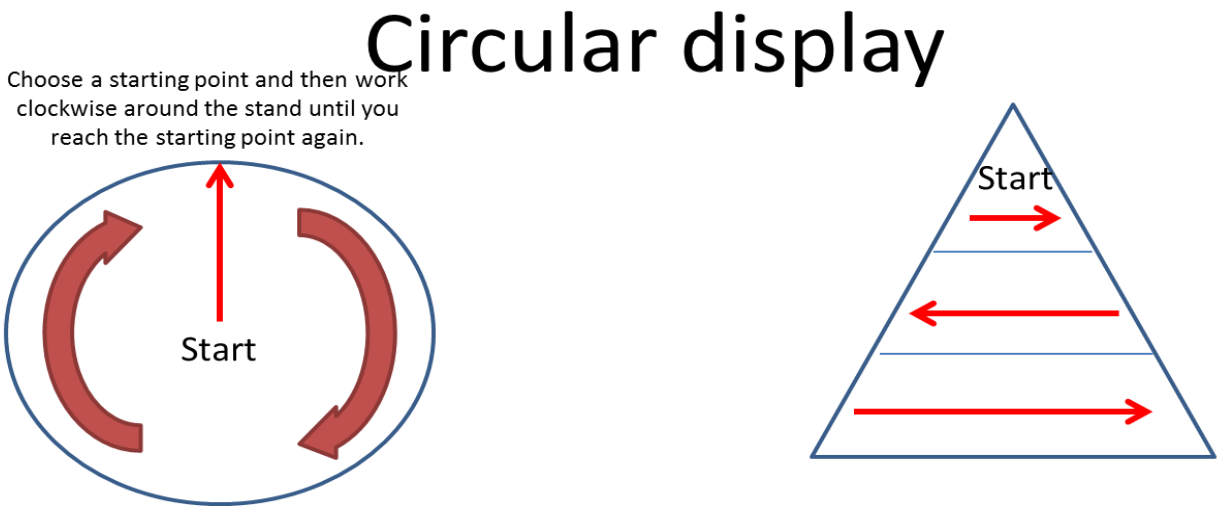
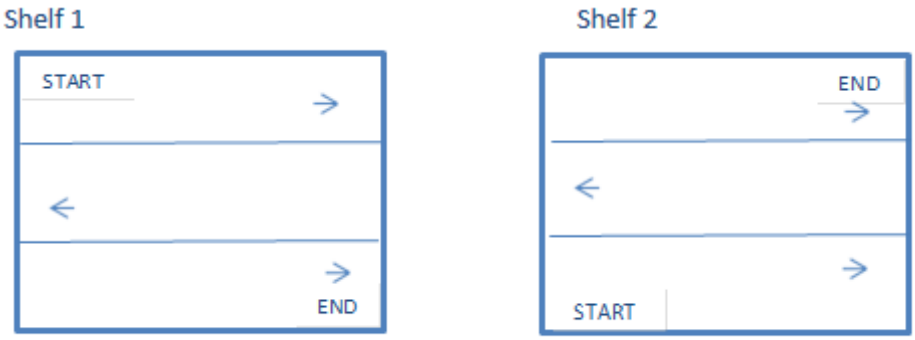


Diagram 3: steps taken to minimise bias caused by underestimating the number of products in a given section

Systematic bias may be introduced if a researcher frequently underestimates the number of products per section as not all the products will stand an equal chance of being selected. However, using the directions and suggested ordering should minimise any effect this may have. If the estimates are consistently too low then the bias would be that products on the bottom shelf were less likely to be sampled. A possible solution would be to alternate the order of the shelf counting, this would mean that when a section estimate is smaller than the number of products on the shelf then either the top shelf or bottom shelf(depending on the 'starting' position') will be less likely to be sampled.



Appendix D CLYMBOL Research task 1.3 data extraction protocol

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Note: This protocol was circulated to all task partners involved in the data collection for the CLYMBOL project: EUFIC, University of Ljubljana, University of Surrey, University of Oxford, Saarland University, Agrifood Research and Technology Centre of Aragon.

Background

The objective of Task 1.3 is to deliver a database which will measure the prevalence of health and nutrition claims in the UK, the Netherlands, Germany, Slovenia and Spain. The database will also be used in tasks 1.4 (Analysis of the nutritional composition of foods bearing health related symbols and claims) and task 1.5 (A comparative analysis of the nutritional criteria for health-related symbols).

This document will provide guidance on how to use the **'Data extraction product sampling_CLYMBOL WP1 task 1.3'** Excel workbook. The workbook uses drop-down menus for some variables, whereas other variables allow text or numbers to be entered. Where drop-down menus are used this document will list the permitted responses and also indicate where free text may be entered. For some sections additional guidance will also be provided (in italics).

Information on how to categorise claims is provided in the Task 1.3 protocol and the final Taxonomy that was developed in Task 1.2.

General note: Missing data should be marked with a period or 'NA' where appropriate

PRODUCT INFORMATION SHEET Section 1

Country		
UK	Netherlands	Switzerland
Slovenia	Spain	
Store type		
Supermarket	Discounter	Neighbourhood
Notes: Store names and addresses should not be entered on this spread sheet but should be sent to the Task leader in preparation for the final report.		
Product code		

FREE TEXT	*Notes: Products from each country will be numbered consecutively from 1 to 400.*	
Product name		
FREE TEXT	*Notes: The product name should be entered in the following format: "Company name brand name product name package size (e.g. in grams or ml/l". If the company name is not in a prominent position on the packaging then the company name may be omitted and the brand name (which includes the flavour/variation) should be written instead (e.g. Britvic's Diet Pepsi may be recorded as 'Diet Pepsi').*	
Food category (Dunford et al. 2012)		
Fruit and vegetable juices	Soft drinks	Cordials
Coffee and tea	Electrolyte drinks	Alcoholic Beverages
Waters	Bread	Biscuits
Cakes, muffins & pastry	Cereal bars	Noodles
Breakfast cereal	Pasta	Maize
Corn	Rice	Couscous
Unprocessed cereals	Chocolate & sweets	Jelly
Chewing gum	Pizza	Soup
Ready meals	Prepared salads & sandwiches	Other
Cheese	Yoghurt products	Milk
Cream	Deserts	Ice cream and edible ices
Butter & Margarine	Cooking oils	All egg products
Canned fish & seafood	Chilled fish	Frozen fish
Baby food	Vegetables	Fruits
Jams and Spreads	Nuts and Seeds	Processed meat and derivatives
Meat alternatives	Crisps and snacks	Sauces
Mayonnaise / Dressings	Spreads	Honey and Syrups
Price (in Euros)		
FREE TEXT	*Notes: This is the price spent to purchase the product. No further calculations or conversions are required. The price should be recorded as a number with two decimal places (1.25 = 1 Euro and 25 cents)*	
Price (FOR UK ONLY: IN GBP)		
FREE TEXT		
Nutritional declaration (tables, lists etc.)		
1	0	

Notes: nutritional declaration refers to statements regarding the presence or absence of nutrients.

Nutrient specific systems

None	GDA's	Traffic lights
GDA+TLL	Other	

Notes: Nutrient specific systems is supplementary nutrition information which displays the amount of select nutrients from the nutrient declaration using numbers including % Daily Values (%DV) or % guideline daily amounts (%GDA) or words such as "high," "medium," or "low" or traffic-light colours or symbols
GDA: Guideline daily amounts or recommended daily allowance of specific nutrients.
TLL: Traffic light labelling is a colour coded food labelling system that indicates high (red), medium (amber) or low (green) levels of nutrients. This can appear independently or combined with GDA's or other product information.

Nutrient specific system position

FOP	FOP+	NOT-FOP

Notes: FOP: Front of pack

FOP+: Front of pack and at least one other location (e.g. the side or back of the product packaging)

NOT-FOP: Not front of packet location

Summary indicator systems (e.g. 1-100 healthiness ratings) Y = 1/N = 0		
1	0	

Notes: Summary indicator systems refer to supplementary nutrition information which uses a single symbol, icon, or score to provide summary information about the nutrient content of a product.

Further details of summary indicator systems

FREE TEXT

List of ingredients Y = 1/N = 0

1	0	

Notes: Does the product packaging contain any nutritional information?

Dairy/Lactose free - *worded or symbolic*Y = 1/N = 0		
1	0	

Notes: Does this statement appear anywhere on the product packaging (other than in the ingredient/product information panel)?

Wheat/gluten free - *worded or symbolic* Y = 1/N = 0

1	0	

Notes: Does this statement appear anywhere on the product packaging (other than in the ingredient/product information panel)?

Vegetarian - *worded or symbolic* Y = 1/N = 0

1	0	
Notes: Does this statement appear anywhere on the product packaging (other than in the ingredient/product information panel)?		
"no artificial preservatives" Y = 1/N = 0		
1	0	
Notes: Does this statement appear anywhere on the product packaging (other than in the ingredient/product information panel)?		
"no artificial colours" Y = 1/N = 0		
1	0	
Notes: Does this statement appear anywhere on the product packaging (other than in the ingredient/product information panel)?		
"no artificial flavours" Y = 1/N = 0		
1	0	
Notes: Does this statement appear anywhere on the product packaging (other than in the ingredient/product information panel)?		
Other:		
FREE TEXT		
Notes: Please use this column to enter details or problems that you have had entering the details for the current product		
PRODUCT INFORMATION SHEET Section 2		
Manufacturer-provided nutritional information (in grams per 100grams unless specified otherwise)		
Notes: In order to run the nutrient profile models (to be discussed in the Task 1.4 protocol) some nutritional information is required. Nutritional information should be taken from the product packaging and recorded in grams per 100grams. Where manufactures only provide the nutritional information by serving size this will need to be converted into a g/100g format. The nutritional information should be recorded as per intended consumption (please see Appendix A for further information), for example the nutritional information for fruit cordials, dry sauces etc. should be recorded after dilution/preparation. Missing data should be recorded with a period; this will be supplemented with local food tables at a later date. **Where 'trace' amounts are listed please record this as zero.**		
Recommended serving size (grams)		
Numerical data only	*Notes: In the first instance this should be recorded from the product packaging. Where this information is unavailable a standardised food portion guide should be used, for example for data collected in the UK, please use the Food Standards Agency's Food Portion Sizes (third edition) published by the Fisheries & Food Ministry of Agriculture. If missing values still remain please make an estimate based on a similar product. Estimates should be marked by changing*	

	the colour of the text to red.
Energy (KJ per 100g)	
Numerical data only	
Energy (kcal/100g)	
Numerical data only	
Protein	
Numerical data only	
Carbohydrate	
Numerical data only	
Total sugars	
Numerical data only	
Total fat	
Numerical data only	
Saturated fat	
Numerical data only	
Fibre	
Numerical data only	
Sodium (mg/100g)	
Numerical data only	*Notes: To convert salt values to sodium, divide the amount of salt by 2.5.*

Section 3: Additional information required for nutrient profiling

Notes: This section collects information about the composition of the product in terms of its ingredients. This information should be recorded as grams per 100g grams (i.e. the percentage of ingredient that is found in the product)

Ingredients are normally listed in descending order of the proportion by weight in the food. This may be of some assistance when researchers are making estimates for the following section. In addition to this European guidelines state that QUID (Quantitative Ingredients) declarations are required '…where the ingredient or category of ingredients concerned appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer." (Article 7 (2)(a) of Directive 97/4/EC). Therefore sometimes the percentage of fruit and vegetables, meat, fish, dairy constituents, cereals etc. will be given but where QUID declarations are not present the researcher will have to make an estimate to the nearest 10%.

% fruit and vegetables	
Numerical data only	*Notes: This information may be available in the ingredients list or in the product name; Fruit juices are 100% fruit and vegetables whereas nectars can contain anything between 25-99% fruit juice, whilst fruit juice drinks contain 0-24% fruit content. Where this is not clear please make an estimate to the nearest 10%. Please See Appendix B for further information.*
% meat	
Numerical data only	*Notes: 'Meat' refers to the edible proportion of meat in the product when ready to be consumed. This information may be available in the ingredients list or in the product name, where this is not clear please make an estimate to the nearest 10%.*
% fish	
Numerical data only	*Notes: 'Fish' refers to any fish, shellfish, crustaceans, molluscs and echinoderms. This information may be available in the ingredients list or in the product name, where this is not clear please make an estimate to the nearest 10%.*
% dairy constituents	
Numerical data only	*Notes: 'Dairy' constituents refers to dairy products like milk. This information may be available in the ingredients list or in the product name, where this is not clear please make an estimate to the nearest 10%.*
% of cereals	
Numerical data only	*Notes: Cereals refers to grains only (processed or unprocessed such as wheat, spelt, rye, oats, barley, maize, millet and durra and other Sorghum species). This information may be available in the ingredients list or in the product name, where this is not clear please make an estimate to the nearest 10%.*
% bread/rice/pasta	
Numerical data only	*Notes: This measures the total percentage of bread, rice and pasta within a product. This somewhat overlaps with the 'cereals' percentage as it also contains rice. This information may be available in the ingredients list or in the product name, where this is not clear please make an estimate to the nearest 10%.*
% wholegrain	
Numerical data only	*Notes: 'Wholegrain' refers to the whole grain of cereals (bran, germ and endosperm); the grain may be ground, crushed etc. Where the whole grain of cereal is crushed or ground the original amount of whole grain should be entered). This information may be available in the ingredients list or in the product name, where this is not clear please make an estimate to the nearest 10%.*
FRO SOY BASED PRODUCTS ONLY: % soy protein	
numerical data only	*Notes: Soy products include soya milk, soya burgers or any food where soya is the main protein component. This information may be*

	available in the ingredients list or in the product name, where this is not clear please make an estimate to the nearest 10%.	

Nutrient profile model food groups

EU Model March 09		
Vegetable oils, butter and spreadable fats as defined in Article 115 and Annex XV of EC no 1234/2007	Products of fruit and vegetables products except oils	Seeds products, except oils
Meat based products	Fishery products, crustaceans and molluscs	Dairy products (except cheese)
Cheeses	Cereal and cereal products except breakfast cereals and fine bakery wares	Biscuits and other fine bakery wares
Breakfast cereals	Soups	Soy products containing between 3-10% soy protein
Soy based products more than 10% soy protein	Non-alcoholic beverages (not belonging in other categories)	Other foods (that do not qualify for above categories)

Notes: Full category names listed below:

1. Vegetable oils, butter and spreadable fats as defined in Article 115 and Annex XV of Council Regulation (EC) No 1234/2007

2a. Products of fruits and vegetables, except oils (minimum 50g of fruit/vegetable per 100g product except nectars

2b. Seeds products, except oils (minimum 50g nut per 100g)

3. Meat based products (minimum 50g meat per 100g)

4. Fishery products, crustaceans, and molluscs (minimum of 50g fish, crustaceans, and/or molluscs per 100g)

5a: Dairy products, except cheeses (minimum 50gdairy constituents, except drinks based on fermented milks

5b. Cheeses (minimum 50g of dairy constituents)

6a. Cereal and cereal products except breakfast cereals and fine bakery wares (minimum 50g cereals)

6b. Biscuits and other fine bakery wares (minimum 30g cereals per 100g)

6c. Breakfast cereals (minimum 50g of cereals per 100g)

7a. Soups (minimum 200g per serving)

7b. Ready meals and sandwiches (minimum 200g serving size, minimum 2 of the following 30g fruits, vegetables and/or nuts, 30g cereals, 30g meat, 30 fish and/or 30g milk.

8a. Soy based products containing between 3-10% soy protein

8b. Soy based products containing more than 10% soy protein
9. Non-alcoholic beverages (that do not qualify for one of above categories)
10. Other foods (that do not qualify for one the above mentioned categories

FSANZ Model

Category 1: Beverages	Category 2: Foods other than those in Category 1 or 3, and cheese with calcium content <= 320/100g	Category 3: Cheeses with calcium content >320mg/100g, oils, oil spreads, margarines, butter

Keyhole

UNABLE TO CATEGORISE	Milk and corresponding fermented products	Flavoured fermented milk products
Vegetable products intended for use as products in Group 1	Products consisting of a mixture or milk and cream and intended for the same uses of cream, and the corresponding fermented products (may be flavoured)	Products wholly or partially of vegetable origin (same uses as group 4)
Fresh cheese and corresponding flavoured products	Margarine/soft cheese	Other cheese and corresponding flavoured products
Edible fats and blends	Oil and liquid margarine and liquid blends	Untreated meat
Untreated fish	Products containing at least 50% meat	Products containing at least 50% fish etc.
Ready prepared products intended to constitutes a main meal containing 400-750 kcal and 25% root vegetables,	Pirogues, pizzas and non-dessert pie based on cereal	Sandwiches, baguettes, wraps and similar products based on cereals
Soups	Fruit and berries	Potatoes, root vegetables, leguminous plants other than peanuts and other vegetables which have not have been processed
Soft bread and bread mixes	Hard bread and rusks	Pasta unfilled
Breakfast cereals and muesli	cereal flour, flakes, grains and crushed cereals	Porridge and porridge powder

Choices International Model

Fresh or frozen fresh fruit, vegetables and legumes	Processed fruit and vegetables	Fruit juices
Water (plain)	potatoes (unprocessed)	Potatoes (processed), pasta, noodles
Rice	Bread	Grains and cereals product

Breakfast cereal products	Meat, poultry, eggs (unprocessed)	Processed meat, meat products, and meat substitutes
Fresh or fresh-frozen fish, shellfish, and crustaceans	Processed fish or fish products	Milk (products)
Cheese (products)	Oils, fats and fat containing spreads	Main dishes
Filled sandwiches/rolls	Soups	Meal sauces
Other sauces (water basis)	Other sauces (emulsion)	Snacks (pastry, edible ice, sweet and savoury snacks)
Beverages	Bread toppings including hummus like products	All other products

Finnish Heart Symbol

UNABLE TO CATEGORISE	Milk, sour milk and other similar products	Yoghurt, quark and similar products (non-drinkable products)
Cultured milk	Cream, crèmes and other similar products used in cooking	Non-ripened cheese and similar products
Cheese spreads and similar products	Cottage cheese	Ripened cheese and similar products
Ice creams, sherbets	Fat spreads	Vegetable oils
Liquid oils	Salad dressings	Mayonnaise, hamburger and sandwich dressings
Whole meat products	Cold cut sausages and sausages to be cooked	Mustards and ketchups
Spices and seasonings	Seasoning and barbecue sauces and marinades	Bouillon in cubes and powdered and concentrated broth
Bread	Crisp bread, Finn crisp	Pastry (sweet and salted), moisture content 0-10 %
Pastry (sweet and salted), moisture content over 10 %	Breakfast cereals (cereals, muesli and alike) , hot cereals, flakes and meal (porridge)	Pasta, rice and similar products
Ready-to-eat food (including meat/fish/vegetables +potato/pasta/rice etc.), meal salads and semi-processed foods prepared according to instructions	Sandwiches and different kind of meals made of bread (e.g. tacos, tortillas, hamburgers, Panini)	Meat, fish and vegetable sauces and semi-processed foods prepared according to instructions
Sauces (meal and food sauces) and semi-processed food prepared according to instructions	Processed foods of fish, meat and vegetables (e.g. meat balls and vegetable patties)	Potato side dishes (e.g. mashed potatoes, potato wedges)
Side salads (mayonnaise and fresh)	Unseasoned meat	Seasoned/marinated meat
Cooked Meat	Fresh or frozen fish	Fresh vegetables, fruits and berries
Processed (e.g. pared, frozen) vegetables, fruits and berries. Also dried berries	Dried peas, beans, chickpeas, lentils and soybean products	Hard, unseasoned tofu
Nuts and seeds		

US FDA Requirements for foods carrying a health claim

UNABLE TO CATEGORISE	Individual food	Meal product
Main dish product		

Notes: For purposes of making a claim, a "meal product shall be defined as a food that:
Makes a major contribution to the total diet by:
Weighing at least 10 ounces (oz.) per labelled serving; and
Containing not less than three 40-g portions of food, or combinations of foods, from two or more of the following four food groups
A) Bread, cereal, rice, and pasta group;
B) Fruits and vegetables group;
C) Milk, yogurt, and cheese group;
D) Meat, poultry, fish, dry beans, eggs, and nuts group; except that;
E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breading's or garnishes; and
Is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, or meal. Such representations may be made either by statements, photographs, or vignettes

For purposes of making a claim, a "main dish product" shall be defined as a food that:
Makes a major contribution to a meal by
Weighing at least 6 oz. per labelled serving; and
Containing not less than 40 g of food, or combinations of foods, from each of at least two of the following four food groups, except as noted in paragraph (E) above
A) Bread, cereal, rice, and pasta group;
B) Fruits and vegetables group;
C) Milk, yogurt, and cheese group;
D) Meat, poultry, fish, dry beans, eggs, and nuts groups; except that:
E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces) gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breading's, or garnishes; and
Is represented as, or is in a form commonly understood to be, a main dish (e.g., not a beverage or a dessert). Such representations may be made either by statements, photographs, or vignettes.

Product information comments

FREE TEXT	*Notes: Please use this section to enter any comments regarding categorising the products into the nutrient profile models' food groups*.

CLAIM INFORMATION SHEET Section 1: Claim characteristics

Notes: Only one claim should be entered on each line, therefore multiple lines will be required for products with more than one claim. Each line must begin with the product code from which the claim was found.

Product code

Number values only	Notes: *This should be the same product code used in PRODUCT INFORMATION SHEET Section 1. This is entered so that each claim can be matched to each product. Columns B and C are provided as a check for researchers to ensure that the correct model and code have been entered.*
Product code	**DO NOT ENTER DATA IN THESE COLUMNS**
Product name	These columns return the values for the current product code that was entered on the previous sheet; this is essentially a check for researchers that the correct code and corresponding product has

	been entered in the claim information sheet.

Claim code

Number values only	*Notes: each claim should have a unique identification code. The ID code should be written as follows: a.b where 'a' refers to the product code and 'b' refers to claim code. For example claim code 2.1, refers to the first claim on the second product, 2.2. the second claim on the second product and so on.*

Claim code (assigned according to EU register for health claims)

Number values only	*Notes: Claim code (EU Register): Using the register circulated by the Task leader, claims should be matched to the EU register where possible.*

Claim description (verbatim in original language)

FREE TEXT

Claim description (translation into English, taken from bilingual list where possible)

FREE TEXT

Number of times the same claim appears on packaging

Number values only

Position

FOP	FOP+	NOT-FOP

Notes: FOP: Front of pack

FOP+: Front of pack and at least one other location (e.g. the side or back of the product packaging)

NOT-FOP: Not front of packet location

Worded or Symbolic or both		
Worded	Symbolic	Combination
Notes: Worded: claim with text only, text on a coloured background, or text within a shape is also considered a 'worded claim' ***Symbolic: A symbol or logo or picture claim that does not use any text (for example a heart symbol).*** ***Combination: A symbol or logo or picture claim that also incorporates text.***		

Target population (if specified)

Not specified	Children	Adults
Women	Men	Elderly
Pregnant women	Other	

If other please specify

FREE TEXT

Nutrient (if specific)

Energy	Fat	Saturated fat

Monounsaturated fat	Polyunsaturated fat	Omega-3 fats
Protein	Fibre	Sugars
Sodium	Cholesterol	Vitamins and minerals (please specify)
Other nutrient		
If other substance/ingredient please specify		
FREE TEXT		
CLAIM INFORMATION SHEET Section 2: CLAIM TYPE		
Nutrition claim		
Health related ingredient claim Y = 1/N = 0		
1	0	
Nutrient content claim Y = 1/N = 0		
1	0	
Nutrient comparison claim Y = 1/N = 0		
1	0	
Health claim		
General health claim Y = 1/N = 0		
1	0	
Nutrient and other function claim Y = 1/N = 0		
1	0	
Reduction of risk claim Y = 1/N = 0		
1	0	
Children's development and health claims Y = 1/N = 0		
1	0	
Effect Direction		
Maintenance	Increase	Reduction
Protection	Normal function/process	Other
Effect certainty		
Without qualifier	helps	contributes
has a role	other	
If other please specify		
FREE TEXT		

Framing	
Positive	Negative
Disease and health state	
FREE TEXT	
Other claim	
FREE TEXT	
Claim comments	
FREE TEXT	

Appendix A: Nutritional information for products not ready for consumption

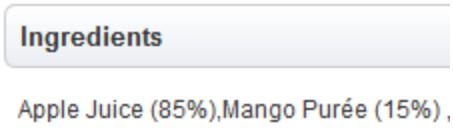
The nutritional information should be recorded as per intended consumption, for example the nutritional information for fruit cordials, dry sauces etc. should be recorded after dilution/preparation. Where foods and drinks have a number of ways of being consumed then the information should be recorded with the least preparation that still renders the product edible/drinkable. Please see the table below for some examples:

Food/Drink	How information may appear on packet	How information should be recorded
Tea bags	Often no nutritional information	Local food tables will be used; values for plain black/herbal/etc. tea with hot water (no milk, no sugar) will be used.
Instant coffee	Often no nutritional information	Local food tables will be used and values for plain, black, instant coffee with hot water will be used.
Instant coffee & sugar & milk pre-mixed sachets	Information per sachet Per serving prepared Dry mix unprepared	In these cases the nutritional information for the product ready to consume should be provided although may need to be converted to g/100g.
Cordials	Per 100ml of undiluted product Per diluted product	The diluted version should always be used.
Raw, fresh meat, fish,	Per raw products Per cooked as per manufacturer's instructions	Per raw product as methods of cooking such as boiling will not add any nutritional value (although the increase of water may lead to the reduction of some values)

Breakfast cereals	Per serving with milk, Per serving without milk Per 100g	Per 100g without milk as the cereal is still edible without milk.
Hot chocolate, malt drinks etc.	Per serving prepared Per 100g unprepared	Per 100g prepared

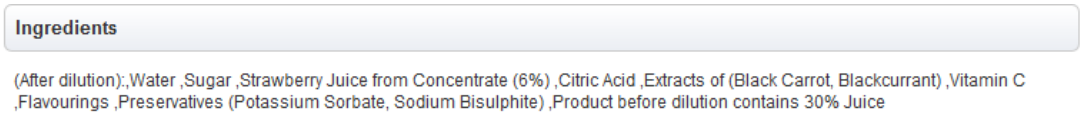
Appendix B: Fruit and vegetable percentages

Example 1. A fruit Juice



In example 1, a fruit juice, we can see that the product is 100% fruit.

Example 2. A fruit cordial



In example 2 the product is 6% fruit as we should aim to record data for food

Appendix E Food categories used in the food label data collection

Source: **Dunford et al. (2012):** International collaborative project to compare and monitor the nutritional composition of processed foods, *European Journal of Preventive Cardiology*, 19(6): pp. 1326–1332.

The categories were designed to be applicable internationally and based on existing food databases.

Food group	Food category	Description
Beverages	Fruit and vegetable juices	Fresh and ambient fruit and vegetable juices
	Soft drinks	Sugar-sweetened and artificially-sweetened soft drinks
	Cordials	Cordials
	Coffee and tea	Coffee and tea products
	Electrolyte drinks	Sports electrolyte drinks
	Alcoholic beverages	All alcoholic beverages
	Waters	Plain and flavoured waters
Bread & bakery products	Bread	White, wholemeal and mixed grain/seed sliced bread and rolls Fruit bread and fruit-based muffins/rolls Wraps and other flatbread products Turkish pide, bagels, English-style muffins, crumpets, pizza bases and other plain bread-based products
	Biscuits	Filled and unfilled sweet biscuits Flavoured and plain crisp bread and crackers
	Cakes, muffins & pastry	Scones, pikelets, doughnuts, cakes, sweet buns, pancakes, crepes, muffins (cake-style), slices etc. Cake, pikelet and pancake dry mixes Sweet pastries (fresh, ambient, chilled and frozen)
Cereal and cereal products	Cereal bars	Plain, chocolate-topped and yoghurt-topped cereal-based bars
	Noodles	Flavoured and plain dry packet and fresh noodles
	Breakfast cereals	Ready to eat breakfast cereals Oats and other breakfast cereals that require heating Other processed cereals (e.g. bran)
	Pasta	Canned and ambient pasta and sauce (with and without meat) products (excludes frozen ready meals) Packaged fresh pasta with sauce Savoury/flavoured dry pasta-based side dishes Plain dry pasta
	Maize (corn)	Tortillas, tamales, tacos and other corn-based cereal products
	Rice	Plain rice

		Savoury rice-based side dishes
	Couscous	Couscous side dishes and plain couscous
	Unprocessed cereals	Flour and other unprocessed cereals (e.g. polenta, psyllium, bread crumbs, yeast)
Confectionary	Chocolate and sweets	Chocolate-based confectionery, sugar-based confectionery
	Jelly	Jelly products and mixes
	Chewing gum	All chewing gums and bubble gum products
Convenience foods	Pizza	Frozen and refrigerated pre-packed pizzas
	Soup	Canned, chilled and ambient soup products
	Ready meals	Frozen, chilled and ambient pre-prepared meals
	Prepared salads and sandwiches	Chilled pre-prepared salads and sandwiches (excluding fast food)
	Other	Other pre-prepared foods such as quiches and pasta
Dairy	Cheese	Feta, haloumi, parmesan and other high-salt cheeses All types of full and reduced fat cheddar/Colby etc. cheese including shredded, block or sliced Soft cheeses such as cream cheese, ricotta and cottage cheese Processed cheese slices and products
	Yoghurt products	Fruit, flavoured and natural yoghurts (full fat, reduced fat and skim varieties) including yoghurt drinks
	Milk	Flavoured and unflavoured dairy milk products Flavoured and unflavoured soymilks Flavoured and unflavoured oat, almond and other milks Condensed, evaporated and powdered milk products (including coconut milk)
	Cream	Thickened, sour and regular cream products
	Deserts	Dairy-based desserts (e.g. custards, rice puddings) Dairy-based dessert mixes (e.g. powders)
	Ice cream and edible ices	Dairy and soy-based ice cream varieties and edible ices
Edible oils and oil emulsions	Butter and margarine	Salted and unsalted butter and margarine products
	Cooking oils	Cooking oils such as olive oil, canola oil and other vegetable oils
Eggs	All egg products	
Fish and fish products	Canned fish and seafood	Plain and flavoured canned tuna, salmon, sardines, anchovies, mackerel, herring, kipper, oysters and shellfish
	Chilled fish	Chilled processed fish products (e.g. smoked salmon)
	Frozen fish	Coated frozen fish products (e.g. fish fingers) and uncoated fish products
Foods for	Baby food	All infant formula products and baby food

specific dietary use		
Fruit and vegetables	Vegetables	Canned tomato products Canned beans and peas Baked beans in tomato sauce (with and without additions) Canned creamed, plain and sweet corn All other canned vegetables Pickled vegetable and olive products Frozen potato-based products Frozen unprocessed vegetables
	Fruit	Dried fruit products including coconut Fruit-based bars Fruit products canned in juice or syrup Fruit gels, fruits in jelly and fruit puree
	Jams and spreads	Jams, marmalades and other preserves
	Nuts and seeds	Salted and unsalted nuts and seeds
Meat and meat products	Processed meat and derivatives	Pre-packed bacon products Beef, pork, chicken and lamb sausages and chilled hot dogs Pre-packaged sliced deli meats Pre-packaged salami and cured meats Beef, pork, chicken and lamb meat burgers Canned meat products (excluding soup and pasta) Frozen meat pies, sausage rolls and other meat-based pastry products such as dim sums
	Meat alternatives	Plain tofu and other meat-free alternatives Meat-free products (e.g. meat-free sausages)
Snack foods	Crisps and snacks	Plain and flavoured potato crisps Plain and flavoured snack foods Extruded snacks (e.g. cheesy snacks) Plain and flavoured corn chips Pretzels, popcorn and other snack foods Other fried snack foods (e.g. plantain chips) All varieties of cracker-based snack packs
Sauces and spreads	Sauces	Table sauces such as tomato sauces and ketchups, sweet chilli, BBQ sauces Steak, HP and Worcestershire sauces Soy, fish, oyster and other Asian high-salt sauces Mustard products Marinade products Meat accompaniments (e.g. apple, cranberry and mint sauces) Plain and flavoured tomato paste products Asian and Indian flavoured powdered, ambient and liquid meal-based sauces Ambient and fresh pasta sauces Recipe bases Liquid and powdered gravies and stock
	Mayonnaise /	Full and low-fat mayonnaise

	Dressings	Oil-based, vinegar-based and other types of salad dressing
	Spreads	Crunchy and smooth salted and unsalted peanut butter Relishes, chutneys and pickles Other savory spreads (e.g. vegetable spreads) Pâté spreads Sweet spreads Yeast-extract spreads (e.g. vegemite) Chilled and ambient dips and salsa
Sugars, honey and related products	Honey and syrups	Honey and syrups Dessert toppings

Appendix F EU nutrient profile model proposed for the use of regulating health and nutrition claims

Draft 17 March 2009

COMMISSION REGULATION (EC) No .../..

of [...]

establishing nutrient profiles provided for in Article 4(1) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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[1], and in particular Article 4(1),

Having consulted the European Food Safety Authority (the Authority),

Whereas:

(1) Regulation (EC) No 1924/2006 lays down harmonized rules for the use of nutrition and health claims on the labelling, presentation and advertising of foods; such claims are intended to highlight a beneficial effect of a food category, a food, or one of its constituents, due to its nutritional properties or to its effect on health.

(2) However, foods promoted with such claims may be perceived by consumers as having an overall nutritional, physiological or other health advantage over similar or other products; it is therefore necessary to avoid situations where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet; to that end, Article 4 of Regulation (EC) No 1924/2006 provides for the setting up of nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims; it also states that the conditions under which foods or categories of foods will be subject to the nutrient profiles shall be established.

(3) Article 4 (1) of Regulation (EC) No 1924/2006 details the elements that shall be taken into account when establishing the nutrient profiles for food and/or certain categories of food, in particular the quantities of certain nutrients and other substances contained in the food, its role, importance and contribution to the diet, and its overall nutritional composition, including the presence of nutrients known as having an effect on health; it also requires that the nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health.

[1] OJ L 404 30.12.2006 p. 9–25 [corrigendum : OJ L 12 18.01.2007 p. 3–18]

EN 1 EN

(4) In accordance with Article 4 (1) of Regulation (EC) No 1924/2006, the Commission has requested the Authority to provide relevant scientific advice in view of establishing the nutrient profiles; on 31 January 2008, the Authority adopted its opinion, providing recommendations on the following: (i) whether profiles should be set for food in general and/or categories of food; (ii) the choice and balance of nutrients to be taken into account; (iii) the choice of reference quantity/basis for profiles (iv) the approach to be used for the calculation of the profiles; and (v) the feasibility and testing of a proposed system;

(5) In accordance with Article 4 (1) of Regulation (EC) No 1924/2006, certain foods or categories of food may be exempted from the requirement to comply with established nutrient profiles, depending on their role and importance in the diet of the population. Certain foods are important basic elements of traditional diets across Europe and as such are important sources of essential nutrients for the population. It would be appropriate for such foods, mainly unprocessed, to be exempted from the scope of application of nutrient profiles in order to avoid potential conflict with efforts at national or Community level to encourage their inclusion in a balanced and diversified diet of the population. Further, when these basic foods are processed they still can give rise to products that are still, to a large extend, good sources of the essential nutrients in question. It would, therefore, be appropriate to set specific nutrient profiles for these categories of processed foods, which take into account these considerations. Other foods or food categories have no significant impact on dietary intakes of the nutrients that will be taken into account for the nutrient profiles and should also be excluded from the scope of application of nutrient profiles,

(6) In addition to being scientifically based, nutrient profiles should also be established in a way that ensures proportionality with the objective to be reached, allows for product innovation and takes due account of the necessary feasibility and simplicity of use by all stakeholders and by controlling authorities as well as, at the same time, of the protection of consumer interests. In compliance with Article 4 (1) of Regulation (EC) No 1924/2006, Member States and stakeholders, in particular food business operators and consumers groups, were consulted by the Commission for setting the nutrient profiles; based on that consultation and the opinion of the Authority, it emerges that it is appropriate to set up a system of nutrient profiles for foods in general, from which adjustments and exemptions should be allowed for a limited number of categories of foods or of specific foods for reasons identified above;

(7) For the sake of clarity, it is appropriate to set specific criteria and conditions with a view to determining which foods and/or categories of foods are covered by these exemptions, and/or by adapted nutrient profiles for certain of them; however, given that specific composition criteria apply to the products covered by Article 115 and annex XV of Regulation (EC) No 1234/2007 of 22 October 2007 laying down standards for spreadable fats, no further conditions are needed for these products to benefit from specific nutrient profiles, while composition criteria should be established for other food categories for which specific nutrient profile applies.

(8) Following Article 4 (1) Regulation (EC) No 1924/2006, nutrient profiles should be established taking into account nutrients that have been scientifically recognised as having an effect on health; the Authority recommended to select nutrients for which there is evidence of a dietary imbalance in European populations that might influence the development of overweight and obesity or diet-related diseases such as cardiovascular disease, or other disorders; they include nutrients that might be consumed in excess, as well as those for which intakes might be inadequate; it therefore advised that nutrient profiles should take into account nutrients consumed in excess, such as fat, saturated fatty acids, trans-fatty acids, sugars, salt/sodium, but also possibly monounsaturated fatty acids, and fibre, whose intakes are often lower than recommended.

(9) Nutrient profile schemes can be very elaborated by taking into account many such nutrients, combining nutrients whose excessive consumption would be detrimental to health and those which would be good to consume at higher amounts. Such elaborated nutrient profile scheme could result in a more refined selection of products that would be allowed to bear claims or not. But the burden imposed to economic operators and to controlling authorities would be disproportionate to the benefits expected from such refinement, as resulted through the testing of the various options on the testing basket of foods devised for this purpose.

(10) Consequently, and for the purpose of better regulation only threshold levels for sodium (salt), saturated fat and sugars should be taken into account for setting of nutrient profiles. Those maximum levels should be set per 100g/ml, which is an efficient, simple and practical reference basis for a category based system limited to nutrients that are consumed in excess.

(11) Such threshold levels should allow nutrition and health claims on the healthier products within each category of the nutrient profiles system, in line with dietary advice developed and promoted by Member States, allowing for product innovation when reformulation opportunities to reduce the exceeding nutrient(s) exist for products exceeding the maximum levels. In some cases, as for food in dried form, such as milk powder and preparations for instant drinks to be reconstituted with water or milk and for foods in concentrated forms such as fruit concentrate, it is appropriate that maximum level for nutrient profiles should apply only to the food as reconstituted, ready for consumption, following manufacturers' instructions.

(12) The monitoring of use and the impact of nutrition and health claims is necessary to identify and measure the nutritional impact of nutrient profiles in the diet, potential distortion on competition, such as higher or lower market share, and potential distortion on consumption patterns, such as a lower consumption due to the prohibition of making a claim.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

1. The nutrient profiles which food or certain categories of food must comply with in order to bear nutrition or health claims, as referred to in Article 4 (1) of Regulation (EC) No 1924/2006, are set out in the Annex.

2. For food in dried form, and for foods in concentrated forms, nutrient profiles referred to in paragraph 1 shall apply to the food as reconstituted following manufacturer instructions.

Article 2

(1) The following foods or food categories are exempted from complying with the nutrient profiles referred to in Article 1 where they bear nutrition or health claims in accordance with Regulation 1924/2006:

(a) Fruits, vegetables, seeds and their products, except vegetable oils, presented fresh, frozen, dried, or under any other form in so far as they contain no added sugars, salt or fat;

(b) Meats and edible meat offal falling within CN code 02;

(c) Fishes and crustaceans, molluscs and other aquatic invertebrates falling within CN codes 03;

(d) Milks falling within CN code 0401 20;

(e) Eggs falling within CN code 0407;

(f) Breads falling within CN code 1905 90 30 and containing at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal;

(g) Honey, as defined in Annex I to Council Directive 2001/110/EC of 20 December 2001 relating to honey[2];

(h) Food supplements as defined in Article 2(a) of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[3];

(i) Table top sweeteners as defined by Article 3(2)(g) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[4];

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[2] OJ L 10, 12.1.2002, p. 47.
[3] OJ L 183, 12.7.2002, p. 51.
[4] OJ L 354 31.12.2008, p. 16.

(j) Cough drops falling within CN code 1704 90 55, chewing gum falling under CN code 1704 10 10, and dextrose tablets.

(2) The following dietetic foods are exempted from complying with the nutrient profiles referred to in Article 1:

(a) Cereal-based foods and baby foods intended for infants and young children covered by Commission Directive 2006/125/EC of 5 December on processed cereal-based foods and baby foods for infants and young children [5];

(b) Foods intended for use in energy-restricted diets for weight reduction covered by Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction [6];

(c) Infant formulae and follow-on formulae covered by Commission Directive 2006/141/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction [7];

(d) Dietary foods for special medical purposes covered by Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[8].

(3) Salt is exempted from complying with the nutrient profiles referred to in Article 1 where they bear nutrition or health claims related to the addition of iodine and / or fluorine.

Article 3

Member States, in collaboration with interested parties, in particular food business operators and consumer groups, shall monitor foods bearing nutrition and health claims on the Community market. The monitoring shall be aimed to identify and measure the nutritional impact of nutrient profiles in the diet and any distortion of competition between different food sectors. It shall be in place when nutrient profiles will apply, in order to provide results for reviewing nutrient profiles after the 3 first years of application.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

In accordance to Article 28 (1) of Regulation (EC) No1924/2006, it shall apply from [date of adoption + 2 years]

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5 OJ L 339, 6.12.2006, p. 16
6 OJ L 139, 31.5.2007, p.22
7 OJ L 401, 30.12.2006, p.130.
8 OJ L 91, 7.4. 1999, p.29.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

For the Commission
[...]
Member of the Commission

ANNEX: specific nutrient profiles and conditions of use, which food or certain categories of food must comply with in order to bear nutrition or health claims

Food category and specific conditions [1]		Thresholds		
		Sodium (mg/100g or 100ml)	Saturates [2] (g/100g or 100ml)	Sugars [2] (g/100g or 100ml)
Vegetable oils, butter and spreadable fats as defined in Article 115 and Annex XV of Council Regulation (EC) No 1234/2007		500	30	10
Products of fruits, vegetables, and seeds, except oils	Products of fruits and vegetables products [4], except oils Minimum 50g of fruit and/or vegetable per 100g of finished products, except for nectars covered by Directive (EC) No 112/2001	400	5	15
	Seeds [4] products, except oils Minimum 50g of nuts per 100g of finished products	400	10	15
Meat based products Minimum 50g of meat per 100g of finished products		800	8	10
Fishery products, crustaceans, and molluscs Minimum 50g of fish, crustaceans, and/or molluscs per 100g of finished products		800	10	10
Dairy products as defined in Council Regulation (EC) No1234/2007, Annex XII	Dairy products, except cheeses Minimum 50g of dairy constituents per 100g of finished products, except for drinks based on fermented milks Minimum 40g per 100g for drinks based on fermented milks	300	2,6	15
	Cheeses Minimum 50g of dairy constituents per 100g of finished products	900	20	15

(1) the minimum quantity required should be calculated on the basis of the ingredients entering into the recipe.

(2) as defined in Council Directive 90/496/EEC.

(3) vegetables include potatoes, beans, and pulses.

(4) seeds include seeds, kernels, nuts. Nuts include peanuts and tree nuts.

Food category and specific conditions		Thresholds		
		Sodium (mg/100g or 100ml)	Saturates (g/100g or 100ml)	Sugars (g/100g or 100ml)
Cereal and cereal products	Cereal and cereal products except breakfast cereals and fine bakery wares Minimum 50g of cereals per 100g of finished products	400	5	15
	Biscuits and other fine bakery wares Minimum 30g of cereals per 100g of finished products for fine bakery wares	500	8	25
	Breakfast cereals Minimum 50g of cereals per 100g of finished products	500	5	25
Ready meals, soups and sandwiches	Soups Minimum 200g per serving size	400	5	10
	Ready meals and sandwiches Minimum 200g per serving size Minimum 2 of the following for: - 30g fruits, vegetables and/or nuts, 30g cereals, 30g meat, 30g fish and/or 30g milk			
Soy based products	Soy based products containing between 3 and 10% soy protein	300	2,6	15
	Soy based products containing more than10% soy protein	800	8	10
Non alcoholic beverages, insofar as they do not qualify for one of the above mentioned food categories		300	2	8
Other foods, insofar as they do not qualify for one of the above mentioned food categories		300	2	10

Appendix G Epidemiological parameters used in the PRIME model

This table of the perimeters used in PRIME was published in Scarborough P, Harrington R, Mizdrak A, Zhou LM, Doherty A (2014). The Preventable Risk Integrated ModEl and its use to estimate the health impact of public health policy scenarios, Scientifica, vol. 2014, Article ID 748750. The table first appeared in: Briggs A, Mizdrak A, Scarborough P. A statin a day keeps the doctor away: comparative proverb assessment modelling study. *BMJ,* 2013;347:f7267

The first column refers to the type of link between the risk factor and health outcome. An explanation of this was given in the article:

"There are six different types of links between risk factors and health outcomes included in the PRIME model that are described in this section. These are links between:

1. Continuous risk factor and a health outcome mediated by a single RR parameter

2. Continuous risk factor and a health outcome mediated by categorical RR parameters

3. Categorical risk factor and a health outcome mediated by categorical RR parameters

4. Energy intake, physical activity and BMI mediated by steady state body weight equations

5. Salt and blood pressure mediated by RCT results

6. Fatty acids and cholesterol mediated by RCT results"

(p3, Scarborough P, Harrington R, Mizdrak A, Zhou LM, Doherty A (2014). The Preventable Risk Integrated ModEl and its use to estimate the health impact of public health policy scenarios, Scientifica, vol. 2014, Article ID 748750)

Link type	Risk factor	Outcome	Unit of change	Relative risk (95% confidence intervals)	Source
1	Fruit	CHD	106g/day increase	0.93 (0.89, 0.96)	Dauchet L, Amouyel P, Hercberg S, Dallongeville J. Fruit and vegetable consumption and risk of coronary heart disease: a meta-analysis of cohort studies. The Journal of nutrition. 2006;136(10):2588-93.
1		Stroke	106g/day increase	0.89 (0.85, 0.93)	Dauchet L, Amouyel P, Dallongeville J. Fruit and vegetable consumption and risk

Link type	Risk factor	Outcome	Unit of change	Relative risk (95% confidence intervals)	Source
					of stroke: a meta-analysis of cohort studies. Neurology. 2005;65(8):1193-7.
1		Lung cancer	80g/day increase	0.94 (0.90, 0.97)	WCRF/AICR. Food, nutrition, physical activity, and the prevention of cancer: a global perspective. Washington DC: AICR, 2007.
1	Vegetables	CHD	106g/day increase	0.89 (0.83, 0.95)	Dauchet L, Amouyel P, Hercberg S, Dallongeville J. Fruit and vegetable consumption and risk of coronary heart disease: a meta-analysis of cohort studies. The Journal of nutrition. 2006;136(10):2588-93.
1	Fibre	CHD	10g/day increase	0.81 (0.72, 0.92)	Pereira MA, O'Reilly E, Augustsson K, Fraser GE, Goldbourt U, Heitmann BL, et al. Dietary fiber and risk of coronary heart disease: a pooled analysis of cohort studies. Archives of internal medicine. 2004;164(4):370-6.
1		Stroke	7g/day increase	0.93 (0.88, 0.98)	Threapleton DE, Greenwood DC, Evans CE, Cleghorn CL, Nykjaer C, Woodhead C, et al. Dietary fiber intake and risk of first stroke: a systematic review and meta-analysis. Stroke; a journal of cerebral circulation. 2013;44(5):1360-8.
1		Colorectal cancer	10g/day increase	Men: 0.88 (0.78, 0.99) Women: 0.92 (0.87, 0.98)	Norat T, Chan D, Lau R, Aune D, Vieira R. WCRF/AICR systematic literature review continuous update project report: the associations between food, nutrition and physical activity and the risk of colorectal cancer. Washington DC: AICR, 2010.
1	Serum cholesterol	CHD	1mmol/l decrease	Under 49: 0.44 (0.42, 0.48) 50-59: 0.58 (0.56, 0.61) 60-69: 0.72 (0.69, 0.74)	Prospective Studies C, Lewington S, Whitlock G, Clarke R, Sherliker

Link type	Risk factor	Outcome	Unit of change	Relative risk (95% confidence intervals)	Source
				70-79: 0.82 (0.80, 0.85) Over 79: 0.85 (0.82, 0.89)	P, Emberson J, et al. Blood cholesterol and vascular mortality by age, sex, and blood pressure: a meta-analysis of individual data from 61 prospective studies with 55,000 vascular deaths. Lancet. 2007;370(9602):1829-39.
1		Stroke	1mmol/l decrease	Under 59: 0.90 (0.84, 0.97) 60-69: 1.02 (0.97, 1.08) 70-79: 1.04 (0.99, 1.09) Over 79: 1.06 (1.00, 1.13)	
1	Blood pressure	CHD	20mmHg SBP decrease	Under 49: 0.49 (0.45, 0.53) 50-59: 0.50 (0.49, 0.52) 60-69: 0.54 (0.53, 0.55) 70-79: 0.60 (0.58, 0.61) Over 79: 0.67 (0.64, 0.70)	Lewington S, Clarke R, Qizilbash N, Peto R, Collins R, Prospective Studies C. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. Lancet. 2002;360(9349):1903-13.
1		Stroke	20mmHg SBP decrease	Under 49: 0.36 (0.32, 0.40) 50-59: 0.38 (0.35, 0.40) 60-69: 0.43 (0.41, 0.45) 70-79: 0.50 (0.48, 0.52) Over 79: 0.67 (0.63, 0.71)	
1		Hypertensive disease	20mmHg SBP decrease	0.22 (0.20, 0.25)	
1		Heart failure	20mmHg SBP decrease	0.53 (0.48, 0.59)	
1		Pulmonary embolism	20mmHg SBP decrease	0.72 (0.60, 0.87)	
1		Rheumatic heart disease	20mmHg SBP decrease	0.74 (0.61, 0.89)	
1		Aortic aneurysm	20mmHg SBP decrease	0.55 (0.49, 0.62)	
1	Body mass index	CHD	5kg/m^2 increase	Men, BMI 15-25: 1.27 (1.16, 1.39) Women, BMI 15-25: 1.01 (0.86, 1.18) Men, BMI 25-50: 1.42 (1.35, 1.48) Women, BMI 25-50: 1.35 (1.28, 1.43)	Prospective Studies C, Whitlock G, Lewington S, Sherliker P, Clarke R, Emberson J, et al. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. Lancet. 2009;373(9669):1083-96.
1		Stroke	5kg/m^2 increase	BMI 15-25: 0.92 (0.82, 1.03) BMI 25-50: 1.39 (1.31, 1.48)	
1		Heart failure	5kg/m^2 increase	BMI 15-25: 0.93 (0.66, 1.29) BMI 25-50: 1.86 (1.55, 2.23)	
1		Diabetes	5kg/m^2 increase	BMI 15-25: 0.96 (0.59, 1.55) BMI 25-50: 2.16 (1.89, 2.46)	
1		Hypertensive disease	5kg/m^2 increase	BMI 15-25: 1.17 (0.77, 1.76) BMI 25-50: 2.03 (1.75, 2.36)	
1		Pancreas cancer	5kg/m^2 increase	1.14 (1.07, 1.22)	WCRF/AICR. Food, nutrition, physical activity, and the prevention of cancer: a global perspective. Washington DC: AICR, 2007.
1		Colorectum cancer	1kg/m^2 increase	1.03 (1.02, 1.04)	
1		Breast cancer	2kg/m^2 increase	Under 60: 0.94 (0.92, 0.95) Over 60: 1.03 (1.01, 1.04)	
1		Endometrial cancer	5kg/m^2 increase	1.52 (1.35, 1.72)	
1		Kidney cancer	5kg/m^2 increase	1.31 (1.24, 1.39)	
1		Gallbladder	5kg/m^2 increase	1.23 (1.15, 1.32)	

Link type	Risk factor	Outcome	Unit of change	Relative risk (95% confidence intervals)	Source
		cancer			
1		Kidney disease	5kg/m^2 increase	BMI 15-25: 1.14 (0.74, 1.77) BMI 25-50: 1.59 (1.27, 1.99)	Prospective Studies C, Whitlock G, Lewington S, Sherliker P, Clarke R, Emberson J, et al. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. Lancet. 2009;373(9669):1083-96.
1		Liver disease	5kg/m^2 increase	BMI 15-25: 0.73 (0.54, 1.00) BMI 25-50: 1.79 (1.54, 2.08)	
2	Alcohol	CHD	Categorical, baseline zero consumption	<2.5g/d: 0.92 (0.80, 1.06) 2.5-15g/d: 0.79 (0.73, 0.86) 15-30g/d: 0.79 (0.71, 0.88) 30-60g/d: 0.77 (0.72, 0.83) 60+g/d: 0.75 (0.53, 0.89)	Ronksley PE, Brien SE, Turner BJ, Mukamal KJ, Ghali WA. Association of alcohol consumption with selected cardiovascular disease outcomes: a systematic review and meta-analysis. Bmj. 2011;342:d671.
2		Stroke	Categorical, baseline zero consumption	<2.5g/d: 1.00 (0.75, 1.34) 2.5-15g/d: 0.86 (0.75, 0.99) 15-30g/d: 1.15 (0.86, 1.54) 30-60g/d: 1.10 (0.85, 1.45) 60+g/d: 1.44 (0.99, 2.10)	
2		Diabetes	Categorical, baseline zero consumption	<6g/d: 0.73 (0.62, 0.86) 6-12g/d: 0.73 (0.62, 0.86) 12-24g/d: 0.66 (0.59, 0.75) 24-48g/d: 0.74 (0.63, 0.88) 48+g/d: 0.93 (0.74, 1.18)	Baliunas DO, Taylor BJ, Irving H, Roerecke M, Patra J, Mohapatra S, et al. Alcohol as a risk factor for type 2 diabetes: A systematic review and meta-analysis. Diabetes care. 2009;32(11):2123-32.
1		M/L/P cancer	Per drink per week	1.24 (1.18, 1.30)	WCRF/AICR. Food, nutrition, physical activity, and the prevention of cancer: a global perspective. Washington DC: AICR, 2007.
1		Colorectal cancer	10g/d increase	1.09 (1.03, 1.14)	
1		Breast cancer	10g/d increase	1.10 (1.06, 1.14)	
1		Liver cancer	10g/d increase	1.10 (1.02, 1.17)	
2		Liver cirrhosis	Categorical, baseline zero consumption	Women, <12g/d: 1.90 (1.10, 3.10) Women, 12-24g/d: 5.60 (4.50, 6.90) Women, 24-36g/d: 7.70 (6.30, 9.50) Women, 36-48g/d: 10.10 (7.50, 13.50) Women, 48-60g/d: 14.70 (11.00, 19.60) Women. 60+g/d: 22.70 (17.20, 30.10) Men, <12g/d: 1.00 (0.60, 1.60) Men, 12-24g/d: 1.60 (1.40, 2.00) Men, 24-36g/d: 2.80 (2.30, 3.40)	Rehm J, Taylor B, Mohapatra S, Irving H, Baliunas D, Patra J, et al. Alcohol as a risk factor for liver cirrhosis: a systematic review and meta-analysis. Drug and alcohol review. 2010;29(4):437-45.

Link type	Risk factor	Outcome	Unit of change	Relative risk (95% confidence intervals)	Source
				Men, 36-48g/d: 5.60 (4.50, 7.00) Men, 48-60g/d: 7.00 (5.80, 8.50) Men. 60+g/d: 14.00 (11.70, 16.70)	
3	Tobacco	CHD	Categorical, baseline never smoked	Men, <65, current: 2.60 (2.40, 2.90) Men, <65, former: 1.60 (1.40, 1.70) Men, 65+, current: 1.50 (1.30, 1.60) Men, 65+, former: 1.20 (1.10, 1.30) Women, <65, current: 3.20 (2.80, 3.60) Women, <65, former: 1.40 (1.20, 1.70) Women, 65+, current: 1.70 (1.60, 1.90) Women, 65+, former: 1.40 (1.30, 1.50)	Thun MJ, Apicella LF, Henley SJ. Smoking vs other risk factors as the cause of smoking-attributable deaths: confounding in the courtroom. JAMA : the journal of the American Medical Association. 2000;284(6):706-12.
3		Stroke	Categorical, baseline never smoked	Men, <65, current: 2.40 (1.80, 3.00) Men, <65, former: 1.00 (0.80, 1.40) Men, 65+, current: 1.50 (1.20, 1.80) Men, 65+, former: 1.00 (0.90, 1.20) Women, <65, current: 3.80 (3.10, 4.70) Women, <65, former: 1.50 (1.10, 2.00) Women, 65+, current: 1.60 (1.40, 1.90) Women, 65+, former: 1.20 (1.00, 1.40)	Thun MJ, Apicella LF, Henley SJ. Smoking vs other risk factors as the cause of smoking-attributable deaths: confounding in the courtroom. JAMA : the journal of the American Medical Association. 2000;284(6):706-12.
3		Diabetes	Categorical, baseline never smoked	Current: 1.44 (1.31, 1.58) Former: 1.23 (1.14, 1.33)	Willi C, Bodenmann P, Ghali WA, Faris PD, Cornuz J. Active smoking and the risk of type 2 diabetes: a systematic review and meta-analysis. JAMA : the journal of the American Medical Association. 2007;298(22):2654-64.
3		M/L/P cancer	Categorical, baseline never smoked	Current: 6.98 (3.14, 15.50) Former: 4.65 (3.35, 6.45)	Gandini S, Botteri E, Iodice S, Boniol M, Lowenfels AB, Maisonneuve P, et al. Tobacco smoking and cancer: a meta-analysis. International journal of cancer Journal international du cancer. 2008;122(1):155-64.
3		Oesophagus cancer	Categorical, baseline never smoked	Current: 3.57 (2.63, 4.48) Former: 1.18 (0.73, 1.91)	
3		Lung cancer	Categorical, baseline never smoked	Current: 8.96 (6.73, 12.10) Former: 3.85 (2.77, 5.34)	
3		Pancreas cancer	Categorical, baseline never	Current: 1.70 (1.51, 1.91) Former: 1.18 (1.04, 1.33)	

Link type	Risk factor	Outcome	Unit of change	Relative risk (95% confidence intervals)	Source
			smoked		
3		Endometrium cancer	Categorical, baseline never smoked	Current: 0.74 (0.64, 0.84) Former: 0.88 (0.78, 0.99)	Zhou B, Yang L, Sun Q, Cong R, Gu H, Tang N, et al. Cigarette smoking and the risk of endometrial cancer: a meta-analysis. The American journal of medicine. 2008;121(6):501-8 e3.
3		Kidney cancer	Categorical, baseline never smoked	Current: 1.52 (1.33, 1.74) Former: 1.25 (1.14, 1.37)	Gandini S, Botteri E, Iodice S, Boniol M, Lowenfels AB, Maisonneuve P, et al. Tobacco smoking and cancer: a meta-analysis. International journal of cancer Journal international du cancer. 2008;122(1):155-64.
3		Stomach cancer	Categorical, baseline never smoked	Current: 1.64 (1.37, 1.95) Former: 1.31 (1.17, 1.46)	
3		Liver cancer	Categorical, baseline never smoked	Current: 1.56 (1.29, 1.87) Former: 1.49 (1.06, 2.10)	Lee YC, Cohet C, Yang YC, Stayner L, Hashibe M, Straif K. Meta-analysis of epidemiologic studies on cigarette smoking and liver cancer. International journal of epidemiology. 2009;38(6):1497-511.
3		Cervix cancer	Categorical, baseline never smoked	Current: 1.83 (1.51, 2.21) Former: 1.26 (1.11, 1.42)	Gandini S, Botteri E, Iodice S, Boniol M, Lowenfels AB, Maisonneuve P, et al. Tobacco smoking and cancer: a meta-analysis. International journal of cancer Journal international du cancer. 2008;122(1):155-64.
3		Bladder cancer	Categorical, baseline never smoked	Current: 2.77 (2.17, 3.54) Former: 1.72 (1.46, 2.04)	
3		COPD	Categorical, baseline never smoked	Men, current: 10.80 (8.40, 13.90) Men, former: 7.80 (6.10, 9.80) Women, current: 12.30 (9.90, 15.20) Women, former: 8.90 (7.10, 11.10)	Thun MJ, Apicella LF, Henley SJ. Smoking vs other risk factors as the cause of smoking-attributable deaths: confounding in the courtroom. JAMA : the journal of the American Medical Association. 2000;284(6):706-12.
1	Physical activity	CHD	11.25METhr/wk increase	0.81 (0.75, 087)	Wahid A, Manek N, Nichols M, Kelly P, Foster C, Webster P, Kaur A, Friedemann Smith C, Wilkins E, Rayner M, Roberts N, Scarborough P.
1		Stroke	11.25METhr/wk increase	0.79 (0.68, 0.92)	
1		Heart failure	11.25METhr/wk increase	0.86 (0.82, 0.89)	
1		Breast	11.25METhr/wk	0.91 (0.87, 0.95)	

Link type	Risk factor	Outcome	Unit of change	Relative risk (95% confidence intervals)	Source
		cancer	increase		Quantifying the Association Between Physical Activity and Cardiovascular Disease and Diabetes: A Systematic Review and Meta-Analysis. Journal of the American Heart Association. 2016;5:e002495,
1		Lung cancer	11.25METhr/wk increase	0.74 (0.63, 0.86)	
1		Stomach cancer	11.25METhr/wk increase	0.74 (0.64, 0.85)	
	Food component	**Outcome**	**Unit of change**	**Regression parameter (95% confidence intervals**	**Source**
6	Total fat	Total serum cholesterol (mmol/l)	1% of total calories increase	0.020 (0.010, 0.030)	Clarke R, Frost C, Collins R, Appleby P, Peto R. Dietary lipids and blood cholesterol: quantitative meta-analysis of metabolic ward studies. Bmj. 1997;314(7074):112-7.
6	Saturated fat	Total serum cholesterol (mmol/l)	1% of total calories increase	0.052 (0.046, 0.058)	
6	MUFAs	Total serum cholesterol (mmol/l)	1% of total calories increase	0.005 (-0.001, 0.011)	
6	PUFAs	Total serum cholesterol (mmol/l)	1% of total calories increase	-0.026 (-0.034, -0.018)	
6	Dietary cholesterol	Total serum cholesterol (mmol/l)	1mg/d increase	0.001 (0.001, 0.001)	
5	Salt	Systolic blood pressure (mmHg)	6g/day reduction	-5.80 (-2.50, -9.20)	He FJ, Li J, Macgregor GA. Effect of longer term modest salt reduction on blood pressure: Cochrane systematic review and meta-analysis of randomised trials. Bmj. 2013;346:f1325.
4	Total energy intake / physical activity level	Change in body weight (kg)	1MJ/PAL increase	Men: 17.7 Women: 20.7	Christiansen E, Garby L. Prediction of body weight changes caused by changes in energy balance. European journal of clinical investigation. 2002;32(11):826-30.

Appendix H Complete PRIME results tables

The impact of health-related claims, in different regulatory scenarios, on UK mortality from non-communicable diseases

		'Restricted' models			**'Restricted & reformulated' models**		
Deaths averted or delayed:	***Impact of HRC (M1)***	**2a – FSANZ NPSC**	**3a - US FDA**	**4a - EU model**	**2b – FSANZ NPSC**	**3b - US FDA**	**4b - EU model**
Total	*2808 (-2993, 7392)*	-258 (-6509, 8706)	-1828 (-7614, 5978)	-1189 (-7431, 7584)	4374 (-2569, 14009)	3763 (-3174, 13225)	3151 (-3783, 12296)
Under 75	*1034 (-845, 2540)*	-322 (-2332, 2553)	-700 (-2562, 1793)	-603 (-2622, 2200)	1439 (-804, 4492)	1584 (-654, 4561)	1067 (-1169, 4021)
Male	*1514 (-1514, 3938)*	-277 (-3582, 4460)	-1019 (-4066, 3048)	-736 (-4096, 3905)	2363 (-1347, 7455)	2220 (-1457, 7162)	1743 (-1960, 6583)
Female	*1294 (-1483, 3466)*	19 (-2946, 4286)	-809 (-3523, 2915)	-453 (-3392, 3719)	2011 (-1259, 6533)	1543 (-1749, 6119)	1408 (-1843, 5795)
Male under 75	*703 (-521, 1714)*	-270 (-1614, 1642)	-490 (-1756, 1129)	-444 (-1804, 1419)	1000 (-512, 3043)	1158 (-338, 3116)	761 (-760, 2720)
Female under 75	*331 (-314, 832)*	-52 (-728, 913)	-210 (-836, 636)	-159 (-847, 806)	439 (-301, 1466)	426 (-325, 1459)	306 (-433, 1332)
Deaths averted or delayed by cause:							
Cardiovascular disease	*2369 (-2340, 6225)*	-347 (-5565, 6946)	-1605 (-6440, 4702)	-1030 (-6256, 6183)	4078 (-1708, 12085)	3648 (-2103, 11352)	3136 (-2793, 10710)
Coronary heart disease	*1344 (-1572, 3908)*	-641 (-4100, 3989)	-1068 (-4289, 2924)	-876 (-4302, 3721)	2481 (-1293, 7628)	2809 (-947, 7536)	2060 (-1874, 6962)
Stroke	*872 (-1201, 2441)*	264 (-1839, 3320)	-446 (-2311, 2226)	-182 (-2322, 2840)	1115 (-1151, 4347)	483 (-1835, 3808)	602 (-1667, 3713)
Heart failure	*34 (-6, 104)*	7 (-31, 55)	-21 (-66, 23)	6 (-33, 57)	109 (37, 202)	80 (20, 165)	107 (34, 205)
Aortic aneurysm	*34 (-6, 102)*	7 (-31, 54)	-20 (-66, 22)	6 (-34, 58)	108 (36, 204)	80 (20, 164)	106 (35, 205)
Pulmonary embolism	*7 (-1, 23)*	1 (-7, 12)	-4 (-15, 4)	1 (-7, 12)	22 (5, 48)	16 (3, 37)	22 (5, 48)
Rheumatic heart disease	*3 (-0, 9)*	1 (-3, 5)	-2 (-6, 2)	1 (-3, 5)	9 (2, 19)	6 (1, 15)	9 (2, 19)
Hypertensive disease	*75 (-13, 222)*	15 (-67, 116)	-45 (-141, 50)	14 (-72, 124)	234 (83, 421)	173 (45, 336)	230 (75, 418)

		'Restricted' models			'Restricted & reformulated' models		
Deaths averted or delayed:	***Impact of HRC (M1)***	**2a – FSANZ NPSC**	**3a - US FDA**	**4a - EU model**	**2b – FSANZ NPSC**	**3b - US FDA**	**4b - EU model**
Diabetes	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Cancer	*439 (-840, 1464)*	89 (-1236, 2030)	-223 (-1403, 1433)	-159 (-1480, 1729)	295 (-1067, 2287)	115 (-1330, 2118)	15 (-1388, 2039)
Mouth, larynx and pharynx	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Oesophagus	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Stomach	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Lung	*392 (-880, 1415)*	129 (-1195, 2014)	-185 (-1371, 1427)	-72 (-1378, 1799)	191 (-1148, 2155)	48 (-1376, 2062)	-19 (-1421, 1974)
Pancreas	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Colorectum	*47 (-85, 181)*	-40 (-248, 289)	-38 (-231, 225)	-87 (-282, 196)	104 (-146, 532)	67 (-147, 402)	34 (-197, 415)
Breast	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Endometrium	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Gallbladder	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Kidney	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Bladder	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Liver	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Cervix	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Chronic obstructive pulmonary disease	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Kidney disease	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Liver disease	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Deaths averted or delayed by behavioural risk factor:							
Diet (excluding obesity)	*2808 (-2993, 7392)*	-258 (-6509, 8706)	-1828 (-7614, 5978)	-1189 (-7431, 7584)	4374 (-2569, 14009)	3763 (-3174, 13225)	3151 (-3783, 12296)
Fruit and vegetables	*1110 (-4605, 5146)*	995 (-4737, 9177)	-572 (-5744, 6795)	476 (-5336, 8396)	1198 (-4729, 9478)	79 (-6190, 8817)	656 (-5394, 9068)
Fibre	*428 (-779, 1478)*	-366 (-1989, 2651)	-346 (-1899, 2107)	-788 (-2259, 1812)	982 (-1295, 5045)	627 (-1212, 3771)	319 (-1723, 3793)
Fats	*610 (-9, 1312)*	-1025 (-1768, -349)	-517 (-1051, 10)	-1006 (-1737, -332)	182 (-947, 1229)	1577 (715, 2593)	180 (-922, 1197)
Salt	*648 (-109, 1924)*	129 (-579, 1020)	-387 (-1230, 437)	121 (-634, 1095)	2052 (716, 3776)	1511 (387, 3034)	2016 (651, 3781)
Physical activity (excluding obesity)	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Alcohol	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)

		'Restricted' models			'Restricted & reformulated' models		
Deaths averted or delayed:	***Impact of HRC (M1)***	**2a – FSANZ NPSC**	**3a - US FDA**	**4a - EU model**	**2b – FSANZ NPSC**	**3b - US FDA**	**4b - EU model**
consumption							
Smoking	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Deaths averted or delayed:							
Total	*4141 (-2220, 9419)*	996 (-5632, 9519)	-2739 (-8873, 5246)	-1158 (-7861, 7965)	9450 (2468, 18851)	7084 (-278, 16140)	6795 (-203, 15755)
Under 75	*1471 (-537, 3171)*	91 (-2070, 2809)	-998 (-3012, 1500)	-592 (-2731, 2319)	3105 (877, 6118)	2662 (337, 5523)	2260 (1, 5172)
Male	*2346 (-1019, 5215)*	517 (-3115, 5048)	-1588 (-4932, 2633)	-717 (-4367, 4083)	5643 (1854, 10629)	4336 (322, 9109)	4075 (232, 8808)
Female	*1795 (-1221, 4188)*	479 (-2619, 4516)	-1150 (-3973, 2583)	-441 (-3584, 3897)	3807 (453, 8382)	2748 (-675, 7040)	2720 (-628, 7051)
Male under 75	*1034 (-308, 2196)*	46 (-1409, 1869)	-716 (-2080, 970)	-436 (-1894, 1476)	2290 (769, 4299)	1984 (405, 3872)	1679 (128, 3568)
Female under 75	*437 (-259, 975)*	45 (-656, 981)	-282 (-931, 573)	-156 (-864, 833)	815 (47, 1847)	678 (-93, 1663)	581 (-169, 1576)
Deaths averted or delayed by cause:							
Cardiovascular disease	*3357 (-1704, 7614)*	579 (-4901, 7564)	-2279 (-7238, 4159)	-1007 (-6569, 6201)	7789 (2123, 15415)	6074 (155, 13332)	5803 (18, 13066)
Coronary heart disease	*2104 (-1075, 4975)*	84 (-3567, 4565)	-1587 (-4916, 2409)	-858 (-4589, 3776)	5465 (1568, 10364)	4726 (854, 9332)	4181 (400, 8926)
Stroke	*933 (-1199, 2509)*	311 (-1765, 3187)	-487 (-2441, 2251)	-181 (-2323, 2997)	1240 (-1061, 4423)	587 (-1804, 3721)	712 (-1625, 3750)
Heart failure	*84 (-34, 318)*	52 (-84, 238)	-54 (-272, 59)	8 (-165, 144)	279 (-114, 709)	197 (-70, 531)	233 (-49, 579)
Aortic aneurysm	*34 (-6, 103)*	7 (-31, 54)	-20 (-65, 25)	6 (-33, 56)	108 (37, 204)	80 (20, 164)	106 (34, 203)
Pulmonary embolism	*7 (-1, 23)*	1 (-7, 12)	-4 (-15, 5)	1 (-7, 12)	22 (5, 48)	16 (3, 38)	22 (5, 47)
Rheumatic heart disease	*3 (-0, 9)*	1 (-3, 5)	-2 (-6, 2)	1 (-3, 5)	9 (2, 19)	6 (1, 15)	9 (2, 20)
Hypertensive disease	*192 (-36, 571)*	124 (-126, 412)	-124 (-460, 89)	17 (-290, 263)	667 (195, 1200)	461 (100, 894)	541 (150, 977)
Diabetes	*76 (-79, 380)*	70 (-101, 305)	-52 (-337, 99)	2 (-226, 189)	277 (-239, 847)	187 (-134, 604)	203 (-159, 654)

		'Restricted' models			'Restricted & reformulated' models		
Deaths averted or delayed:	***Impact of HRC (M1)***	**2a – FSANZ NPSC**	**3a - US FDA**	**4a - EU model**	**2b – FSANZ NPSC**	**3b - US FDA**	**4b - EU model**
Cancer	*712 (-705, 1860)*	356 (-1060, 2271)	-411 (-1714, 1294)	-153 (-1601, 1815)	1457 (-34, 3569)	861 (-748, 2938)	832 (-743, 2794)
Mouth, larynx and pharynx	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Oesophagus	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Stomach	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Lung	*392 (-930, 1370)*	129 (-1182, 2017)	-185 (-1373, 1445)	-72 (-1370, 1808)	191 (-1146, 2182)	48 (-1367, 2056)	-19 (-1442, 1884)
Pancreas	*42 (-31, 154)*	41 (-42, 141)	-29 (-140, 42)	1 (-103, 86)	181 (25, 384)	116 (-1, 274)	127 (1, 298)
Colorectum	*170 (-84, 459)*	81 (-230, 433)	-123 (-405, 175)	-84 (-391, 236)	630 (220, 1119)	404 (25, 813)	404 (16, 865)
Breast	*13 (-13, 62)*	13 (-16, 55)	-9 (-55, 16)	0 (-37, 33)	56 (-21, 151)	36 (-14, 108)	40 (-15, 113)
Endometrium	*35 (-25, 112)*	34 (-38, 96)	-24 (-101, 33)	1 (-75, 62)	144 (58, 229)	93 (2, 173)	102 (12, 185)
Gallbladder	*6 (-4, 19)*	6 (-6, 17)	-4 (-18, 6)	0 (-13, 11)	25 (10, 42)	16 (0, 31)	18 (2, 33)
Kidney	*54 (-40, 168)*	53 (-56, 146)	-37 (-155, 52)	1 (-115, 98)	230 (94, 351)	147 (4, 271)	161 (19, 287)
Bladder	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Liver	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Cervix	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Chronic obstructive pulmonary disease	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Kidney disease	*16 (-16, 78)*	16 (-20, 65)	-11 (-67, 18)	0 (-49, 41)	66 (-32, 183)	43 (-20, 135)	47 (-26, 144)
Liver disease	*21 (-180, 114)*	-25 (-183, 91)	15 (-97, 152)	-1 (-110, 106)	-140 (-566, 287)	-80 (-411, 186)	-90 (-421, 204)
Deaths averted or delayed by behavioural risk factor:							
Diet (excluding obesity)	*2808 (-3337, 7248)*	-258 (-6568, 8314)	-1828 (-7450, 6024)	-1189 (-7535, 7909)	4374 (-2258, 13847)	3763 (-2835, 12797)	3151 (-3429, 12188)
Diet (including obesity)	*4141 (-2220, 9419)*	996 (-5632, 9519)	-2739 (-8873, 5246)	-1158 (-7861, 7965)	9450 (2468, 18851)	7084 (-278, 16140)	6795 (-203, 15755)
Fruit and vegetables	*1110 (-4807, 5010)*	995 (-4773, 8814)	-572 (-5659, 6724)	476 (-5237, 8746)	1198 (-4536, 9511)	79 (-6111, 8594)	656 (-5454, 8904)

		'Restricted' models			'Restricted & reformulated' models		
Deaths averted or delayed:	***Impact of HRC (M1)***	**2a – FSANZ NPSC**	**3a - US FDA**	**4a - EU model**	**2b – FSANZ NPSC**	**3b - US FDA**	**4b - EU model**
Fibre	*428 (-838, 1479)*	-366 (-2032, 2477)	-346 (-1877, 2260)	-788 (-2271, 1796)	982 (-1320, 5069)	627 (-1261, 3809)	319 (-1671, 3905)
Fats	*610 (-15, 1297)*	-1025 (-1798, -346)	-517 (-1053, 66)	-1006 (-1729, -336)	182 (-910, 1265)	1577 (730, 2568)	180 (-893, 1258)
Salt	*648 (-112, 1899)*	129 (-575, 1007)	-387 (-1230, 481)	121 (-636, 1080)	2052 (703, 3785)	1511 (387, 3041)	2016 (654, 3744)
Physical activity (excluding obesity)	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Physical activity (including obesity)	*1316 (-958, 4215)*	1248 (-1382, 3478)	-901 (-3881, 1258)	31 (-2890, 2249)	5212 (2197, 8158)	3414 (80, 6401)	3724 (442, 6656)
Obesity	*1316 (-958, 4215)*	1248 (-1382, 3478)	-901 (-3881, 1258)	31 (-2890, 2249)	5212 (2197, 8158)	3414 (80, 6401)	3724 (442, 6656)
Alcohol consumption	*0 (-0, 0)*	0 (0, 0)	0 (,)	0 (,)	0 (,)	0 (,)	0 (,)
Smoking	*0 (-0, 0)*	0 (0, 0)	0 (,)	0 (,)	0 (,)	0 (,)	0 (,)

The impact of health-related claims on UK mortality from non-communicable diseases (results for the sensitivity analyses models 1-4)

Deaths averted or delayed:	***Impact of HRC (M1)***	**Sensitivity Model 1 – UK data only**	**Sensitivity Model 2 – Analyses at 'All Foods' level**	**Sensitivity Model 3 – Fruit and vegetables from any source**	**Sensitivity Model 4 – No change in fruit and vegetables**
Total	*2808 (-2993, 7392)*	3459 (-36505, 17803)	3147 (-1662, 8070)	2425 (-625, 7964)	1693 (-692, 6952)
Under 75	*1034 (-845, 2540)*	1308 (-11044, 6198)	1245 (-331, 2885)	913 (-7, 2881)	685 (-33, 2562)
Male	*1514 (-1514, 3938)*	1905 (-18651, 9652)	1778 (-775, 4385)	1317 (-240, 4363)	991 (-225, 3876)
Female	*1294 (-1483, 3466)*	1554 (-17780, 8196)	1369 (-878, 3683)	1107 (-394, 3605)	702 (-460, 3100)
Male under 75	*703*	911	883	625	501

Deaths averted or delayed:	***Impact of HRC (M1)***	**Sensitivity Model 1 – UK data only**	**Sensitivity Model 2 – Analyses at 'All Foods' level**	**Sensitivity Model 3 – Fruit and vegetables from any source**	**Sensitivity Model 4 – No change in fruit and vegetables**
	(-521, 1714)	(-7171, 4296)	(-199, 2000)	(28, 2024)	(14, 1830)
Female under 75	*331 (-314, 832)*	397 (-3879, 1935)	362 (-149, 886)	288 (-39, 855)	183 (-55, 741)
Deaths averted or delayed by cause:					
Cardiovascular disease	*2369 (-2340, 6225)*	3147 (-29493, 15710)	2858 (-1530, 7507)	2072 (-702, 7537)	1646 (-736, 6856)
Coronary heart disease	*1344 (-1572, 3908)*	1892 (-16721, 10402)	1910 (-718, 4510)	1188 (-30, 4697)	1262 (261, 4304)
Stroke	*872 (-1201, 2441)*	893 (-13757, 5379)	711 (-763, 2249)	731 (-507, 2033)	230 (-568, 1532)
Heart failure	*34 (-6, 104)*	81 (-21, 367)	53 (-116, 262)	34 (-111, 265)	34 (-113, 261)
Aortic aneurysm	*34 (-6, 102)*	80 (-21, 375)	53 (-117, 267)	34 (-112, 259)	34 (-112, 262)
Pulmonary embolism	*7 (-1, 23)*	16 (-4, 81)	11 (-25, 57)	7 (-23, 58)	7 (-24, 58)
Rheumatic heart disease	*3 (-0, 9)*	7 (-2, 33)	4 (-10, 23)	3 (-9, 23)	3 (-10, 24)
Hypertensive disease	*75 (-13, 222)*	178 (-47, 836)	116 (-251, 580)	75 (-246, 578)	75 (-239, 583)
Diabetes	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Cancer	*439 (-840, 1464)*	313 (-7534, 2925)	289 (-419, 935)	353 (-195, 729)	47 (-21, 217)
Mouth, larynx and pharynx	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Oesophagus	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Stomach	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Lung	*392 (-880, 1415)*	267 (-7509, 2852)	205 (-486, 837)	306 (-250, 629)	0 (0, 0)
Pancreas	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Colorectum	*47 (-85, 181)*	45 (-497, 325)	84 (-25, 222)	47 (-27, 219)	47 (-21, 217)
Breast	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Endometrium	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Gallbladder	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Kidney	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Bladder	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Liver	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Cervix	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Chronic obstructive pulmonary disease	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Kidney disease	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)

Deaths averted or delayed:	***Impact of HRC (M1)***	**Sensitivity Model 1 – UK data only**	**Sensitivity Model 2 – Analyses at 'All Foods' level**	**Sensitivity Model 3 – Fruit and vegetables from any source**	**Sensitivity Model 4 – No change in fruit and vegetables**
Liver disease	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Fruit and vegetables	*1110 (-4605, 5146)*	681 (-38594, 12176)	355 (-2901, 3038)	730 (-1610, 2491)	0 (0, 0)
Fibre	*428 (-779, 1478)*	415 (-4697, 2654)	762 (-233, 1809)	428 (-281, 1776)	428 (-204, 1772)
Fats	*610 (-9, 1312)*	815 (-867, 3214)	1015 (367, 1785)	610 (365, 1735)	610 (373, 1778)
Salt	*648 (-109, 1924)*	1527 (-406, 7039)	998 (-2204, 4916)	648 (-2132, 4960)	648 (-2072, 5012)
Physical activity (excluding obesity)	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Alcohol consumption	*0 (-, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Smoking	*0 (-, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Deaths averted or delayed:					
Total	*4141 (-2220, 9419)*	5336 (-34914, 26221)	7848 (2106, 14350)	3757 (2823, 14206)	3025 (2800, 13172)
Under 75	*1471 (-537, 3171)*	1923 (-10497, 8743)	2782 (969, 4935)	1349 (1160, 4815)	1121 (1164, 4532)
Male	*2346 (-1019, 5215)*	3073 (-17804, 14623)	4666 (1521, 8294)	2148 (1871, 8185)	1823 (1886, 7682)
Female	*1795 (-1221, 4188)*	2262 (-17175, 11699)	3183 (515, 6247)	1608 (864, 6157)	1202 (798, 5717)
Male under 75	*1034 (-308, 2196)*	1377 (-6785, 6134)	2036 (770, 3531)	956 (896, 3495)	832 (911, 3277)
Female under 75	*437 (-259, 975)*	546 (-3732, 2660)	746 (169, 1417)	394 (248, 1373)	289 (231, 1273)
Deaths averted or delayed by cause:					
Cardiovascular disease	*3357 (-1704, 7614)*	4540 (-28625, 21410)	6349 (1405, 12137)	3058 (1863, 11952)	2633 (1969, 11254)
Coronary heart disease	*2104 (-1075, 4975)*	2958 (-16320, 14344)	4542 (1406, 7952)	1945 (1938, 8054)	2021 (2259, 7675)
Stroke	*933 (-1199, 2509)*	982 (-13957, 6018)	969 (-625, 2678)	792 (-422, 2549)	291 (-509, 2057)
Heart failure	*84*	152	238	84	84

Deaths averted or delayed:	***Impact of HRC (M1)***	**Sensitivity Model 1 – UK data only**	**Sensitivity Model 2 – Analyses at 'All Foods' level**	**Sensitivity Model 3 – Fruit and vegetables from any source**	**Sensitivity Model 4 – No change in fruit and vegetables**
Aortic aneurysm	*34 (-6, 103)*	80 (-23, 361)	53 (-107, 271)	34 (-112, 259)	34 (-117, 264)
Pulmonary embolism	*7 (-1, 23)*	16 (-4, 80)	11 (-23, 59)	7 (-24, 59)	7 (-25, 57)
Rheumatic heart disease	*3 (-0, 9)*	7 (-2, 32)	4 (-9, 23)	3 (-9, 23)	3 (-10, 23)
Hypertensive disease	*192 (-36, 571)*	345 (-243, 2193)	532 (-7, 1344)	192 (-16, 1306)	192 (-27, 1320)
Diabetes	*76 (-79, 380)*	107 (-287, 1333)	278 (-95, 853)	76 (-96, 877)	76 (-117, 843)
Cancer	*712 (-705, 1860)*	693 (-7190, 4468)	1215 (262, 2225)	626 (395, 2031)	320 (391, 1768)
Mouth, larynx and pharynx	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Oesophagus	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Stomach	*0 (-0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Lung	*392 (-930, 1370)*	267 (-7622, 2971)	205 (-493, 857)	306 (-260, 646)	0 (0, 0)
Pancreas	*42 (-31, 154)*	58 (-149, 504)	141 (16, 328)	42 (19, 326)	42 (17, 333)
Colorectum	*170 (-84, 459)*	217 (-554, 1311)	501 (183, 892)	170 (186, 884)	170 (188, 889)
Breast	*13 (-13, 62)*	19 (-55, 194)	46 (-15, 136)	13 (-14, 134)	13 (-15, 139)
Endometrium	*35 (-25, 112)*	49 (-111, 394)	120 (37, 229)	35 (39, 226)	35 (39, 230)
Gallbladder	*6 (-4, 19)*	8 (-20, 64)	20 (6, 39)	6 (7, 38)	6 (6, 38)
Kidney	*54 (-40, 168)*	75 (-177, 559)	182 (57, 332)	54 (62, 329)	54 (62, 331)
Bladder	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Liver	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Cervix	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Chronic obstructive pulmonary disease	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Kidney disease	*16 (-16, 78)*	23 (-67, 253)	57 (-20, 173)	16 (-16, 174)	16 (-22, 172)
Liver disease	*21 (-180, 114)*	28 (-402, 428)	51 (-367, 292)	21 (-357, 303)	21 (-381, 295)
Diet (excluding obesity)	*2808 (-3337, 7248)*	3459 (-36875, 17738)	3147 (-1510, 8260)	2425 (-724, 7950)	1693 (-719, 6942)
Diet (including obesity)	*4141 (-2220, 9419)*	5336 (-34914, 26221)	7848 (2106, 14350)	3757 (2823, 14206)	3025 (2800, 13172)
Fruit and	*1110*	681	355	730	0 (0, 0)

Deaths averted or delayed:	***Impact of HRC (M1)***	**Sensitivity Model 1 – UK data only**	**Sensitivity Model 2 – Analyses at 'All Foods' level**	**Sensitivity Model 3 – Fruit and vegetables from any source**	**Sensitivity Model 4 – No change in fruit and vegetables**
vegetables	*(-4807, 5010)*	(-39181, 12445)	(-2913, 3052)	(-1609, 2449)	
Fibre	*428 (-838, 1479)*	415 (-4880, 2638)	762 (-206, 1771)	428 (-234, 1813)	428 (-240, 1788)
Fats	*610 (-15, 1297)*	815 (-906, 3118)	1015 (365, 1787)	610 (365, 1795)	610 (357, 1755)
Salt	*648 (-112, 1899)*	1527 (-442, 6917)	998 (-2060, 5071)	648 (-2123, 4898)	648 (-2202, 4980)
Physical activity (excluding obesity)	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Physical activity (including obesity)	*1316 (-958, 4215)*	1840 (-4063, 15983)	4615 (1357, 8821)	1316 (1500, 8860)	1316 (1487, 8803)
Obesity	*1316 (-958, 4215)*	1840 (-4063, 15983)	4615 (1357, 8821)	1316 (1500, 8860)	1316 (1487, 8803)
Alcohol consumption	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)
Smoking	*0 (0, 0)*	0 (0, 0)	0 (0, 0)	0 (0, 0)	0 (0, 0)