Labelling Approaches for Supplemented Foods

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Abstract

In recent years, natural health products in food formats with higher levels of added vitamins and minerals, amino acids, herbal ingredients and bioactives sought and were granted market access in Canada. Since these food products, referred to as supplemented foods (SFs), are sold alongside conventional foods and lack features that clearly distinguish them from other foods, there is a potential for confusion among consumers as to the appropriate use of these products. There is no research evaluating the nutrition labelling approaches for these foods, and what consumers need in a labelling approach to be able to identify these food products and distinguish them from other foods, determine what the supplemental ingredients are and understand any directions or cautions for use of these foods. To determine key components of an appropriate labelling approach, interviews and discussion groups were conducted in the National Capital Region and the surrounding area to assess consumer access, understanding and appraisal of these foods, using current and tested labelling strategies. Consumer feedback consistently indicated that the current labelling is insufficient for awareness, understanding, appraisal and appropriate use of supplemented foods. Tested labelling components that facilitated awareness, understanding, and appraisal of supplemented foods included a symbol based supplemented food product identifier with the wording "Supplemented" on the front of the package, a "Supplemented" information box containing a listing of the name and amount of each supplemental ingredient and cautionary labelling in proximity to the supplemental ingredient labelling. These key labelling components are to be integrated into a web-based mock-package trial that will objectively test these labelling tools on a large sample of Canadian consumers (n=4000).

Résumé

Au cours des dernières années, des produits de santé naturels sous forme d'aliments contenant une teneur élevée de vitamines/minéraux, des acides aminés, des herbes et des ingrédients bioactifs ont été mis sur le marché canadien. Ces aliments, appelés Aliments Supplémentés, sont vendus avec d'autres produits non-supplémentés. Ceci engendre un risque de confusion chez les consommateurs en ce qui concerne l'utilisation appropriée de ces produits. Aucune étude antérieure n'a évalué une approche d'étiquetage nutritionnelle pour ces aliments ni ce que les consommateurs ont de besoin pour identifier et distinguer ces aliments des autres. Ceci inclut ce qu'ils ont de besoin pour identifier les ingrédients avec lesquels un aliment est supplémenté et toute mise en garde ou directives d'usage liées au produit. Pour déterminer les éléments clés d'une approche d'étiquetage appropriée, des entrevues individuelles et des groupes de discussion ont été menés dans la région de la capitale nationale et aux alentours pour évaluer l'accès, la compréhension et l'évaluation de ses produits par les consommateurs. Des maquettes alimentaires étiquetées avec les stratégies d'étiquetage actuelles et proposées ont été utilisées durant les groupes de discussions. Les consommateurs ont indiqué que l'étiquetage actuel des aliments supplémentés est insuffisant pour la sensibilisation, la compréhension, l'évaluation et l'utilisation appropriée de ces aliments. Les stratégies proposées incluaient un symbole comprenant le mot « supplémenté » sur le devant de l'emballage, une boîte d'information comprenant le type et la quantité de chaque ingrédient avec lequel un aliment est supplémenté et une mise en garde près de cette boîte. Ces composantes d'étiquetage ont été intégrées dans un questionnaire web qui testera ces éléments avec un large échantillon de consommateurs canadiens (n = 4,000).

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List of Abbreviations

% DV	Percent Daily Value
BOP	Back-of-Pack
DG	Discussion Group
DSHEA	Dietary Supplement Health and Education Act
EM	Elizabeth Mansfield
FDA	Food and Drug Administration
FFC	Foods with Function Claims
FNFC	Food with Nutrient Function Claims
FOP	Front-of-Pack
FOSHU	Foods for Specified Health Uses
FSANZ	Food Standards Australia New Zealand
LOI	List of Ingredients
MHLW	Ministry of Health, Labour and Welfare
NFt	Nutrition Facts Table
PDP	Principal Display Panel
PI	Product Identifier
RW	Rana Wahba
SBox	Supplemented Ingredients' Box
SF	Supplemented Food
SFs	Supplemented Foods
TMAL	Temporary Marketing Authorization Letters

Chapter I
Introduction

Shopping for foods has become an increasingly complex task. Not only are consumers exposed to a vast array of foods and a large range of price and product choices within each product category, they are also interacting with a variety of regulated labelling attributes and food industry marketing on the front and back of food labels. The intent of the regulated food labelling information is to enable consumers to make informed food choices. This becomes more important with new or unfamiliar foods and/or when choosing foods to meet specific dietary needs.

With the recent modernization of Health Canada's regulatory regime, a new category of food products which contain added vitamins, minerals, amino acids, herbals or bioactive ingredients have entered the marketplace. These ingredients may perform a physiological role beyond the provision of nutritive requirements (Government of Canada, 2016). Examples of such foods currently on the market include beverages (e.g. vitamin mineral waters, caffeinated energy drinks), beverage mixes and concentrates (e.g. vitamins in granules added to water), bars (e.g. Vitamins A, C and E added to bars) and gums (e.g. vitamins B6 and B12 added to gum). Health Canada calls these "Supplemented Foods (SFs)" (Government of Canada, 2016).

Although there is a long history of foods on the market that have been vitamin/mineral enriched and or fortified according to regulated measures, foods supplemented with certain herbals or bioactives have a limited history of safe use as food (Government of Canada, 2016). Some might not be appropriate for everyone and/or need conditions or directions for safe and appropriate use. Some people might perceive the addition of supplemental ingredients such as vitamins and minerals to foods of otherwise poor nutritional value as an 'added bonus' (Health Canada, 2004). If these supplemented foods are

perceived as healthier and become available in a variety of packaged-foods, there is potential risk of focused consumption of supplemented foods over conventional foods, nutrient imbalances, and intakes approaching or exceeding tolerable upper intake levels for vitamins and minerals (Dietitians of Canada, 2009; Health Canada, 2004; Kalergis & MacDonald, 2009). At present, these supplemented foods lack distinguishing labelling features that clearly identify and distinguish them from other foods, which may potentially lead to inappropriate use of these products and unhealthy dietary changes (e.g. consumers limiting their intake to only packaged supplemented products due to perceived benefit). This reinforces the importance of labelling to ensure that consumers can properly distinguish these foods from conventional products, identify the nature of the supplemental ingredients and understand any directions and/or caution for use.

The overarching goal of this qualitative research is to determine the key components for a set of labelling tools that will assist consumers to:

1- Identify and distinguish SFs from other foods

2- Identify the type and amount of supplemental ingredients

3- Understand any directions or caution associated with particular SF use

We conducted individual interviews and discussion groups throughout the National Capital region and surrounding area with consumers of varying demographics and health literacy levels. The findings from this study are being used to inform a nation-wide mock package trial that is objectively testing the key set of labelling tools identified in our study among a larger sample of Canadians. The latter will serve to inform government in developing labelling regulations for SFs, including design specifications, label placement, and specific templates in accordance with the principles of plain language labelling. It will also be used to support identified education/outreach activities that will be needed to bridge the gaps in consumer understanding and informed use of SFs.

Chapter II
Literature Review

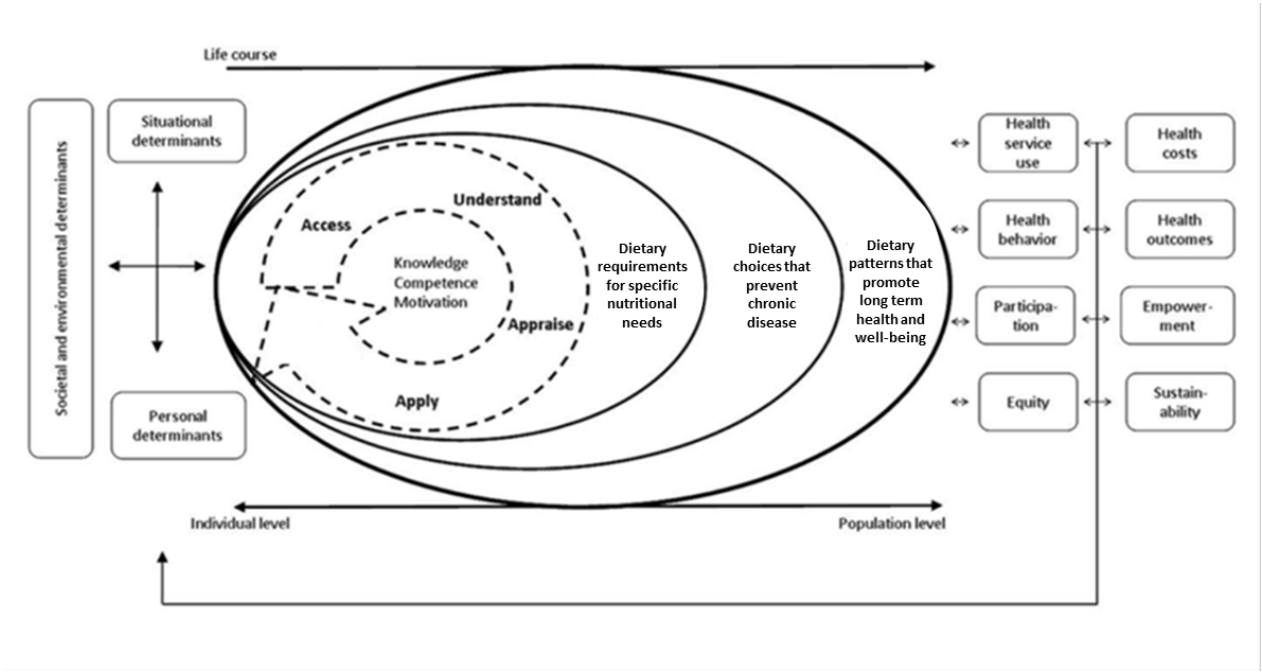
The intent of regulated label information is to enable consumers to make informed food choices (Canada Gazette, 2003). This becomes more important with new or unfamiliar foods, when choosing foods to meet specific dietary needs, or when trying to reduce/increase the amount of certain nutrients. With the recent modernization of Health Canada's regulatory regime, a new category of food products has entered the marketplace. Health Canada is calling these foods "Supplemented Foods (SFs)." They are defined as "a pre-packaged product that is manufactured, sold or represented as a food, which contains added vitamins, minerals, amino acids, herbal or bioactive ingredients. These ingredients may perform a physiological role beyond the provision of nutritive requirements" (Government of Canada, 2016). Examples of such foods currently on the market include beverages (e.g. vitamin mineral waters, caffeinated energy drinks), beverage mixes and concentrates (e.g. vitamins in granules added to water), bars (e.g. bars with added Vitamins A, C and E), and gums (e.g. vitamins B6 and B12 added to gum). Health Canada is currently assessing labelling of these foods to determine gaps in consumer awareness, understanding and appraisal of current supplemented food labelling with the aim of developing a labelling approach that will enable consumers, in particular those that are disadvantaged by marginal or limited health literacy, to identify and distinguish SFs from other foods; identify the type and amount of supplemental ingredients; and understand any directions or caution associated with particular SF use.

While regulated nutrition labeling is the most reported source of nutrition information to guide consumers' food selections (Canadian Council of Food and Nutrition, 2009; Cowburn & Stockley, 2005; Grunert, Wills, et al., 2010), food label use varies considerably amongst Canadians (Grunert, Wills, et al., 2010; Ollberding, Wolf, & Contento, 2010), likely due to the health literacy challenges they face in accessing, understanding, evaluating and using the appropriate nutrition label information to make their

food based decisions (Acton, Vanderlee, Roberto, & Hammond, 2018; Canadian Council of Food and Nutrition, 2009; Cowburn & Stockley, 2005; Goodman, Hammond, Pillo-Blocka, Glanville, & Jenkins, 2011; Hobin et al., 2016; Malloy-Weir & Cooper, 2017). With the introduction of supplemented foods on the market, labelling approaches for these foods need to be explored to ensure that all consumers, particularly those who are limited by health literacy, can find, understand, evaluate and ultimately use nutrition labelling to make more informed supplemented food decisions. For SF label information to be useful, as is the case for any type of labelling, it must be noticed, processed, understood, and evaluated in the context of a consumer's particular dietary goals/needs (Sorensen et al, 2012).

The framework for this SF research study is based on a health literacy conceptual model from Sorensen et al. (2012) (figure 1, below), adapted (with permission from the author) for food-based decision making. This adapted model highlights consumer competencies to access, understand, interpret and evaluate food and nutrition related information to make informed decisions for personal health care, disease prevention and health promotion in an increasingly complex environment. These consumer competencies are influenced by personal (e.g. age, gender, and race) and situational determinants (e.g. social support, family and peer influence) as well as societal and environmental ones, including food industry advertising, food marketing and on-package labelling of nutrition information. Food based decisions are also shaped by consumers' motivation and knowledge of nutrition as they attempt to navigate the increasingly complex food environment to make food choices that meet daily dietary requirements and specific nutritional needs (Grunert, Wills, et al., 2010; Miller & Cassady, 2012; Turner, Skubisz, Pandya, Silverman, & Austin, 2014), all while taking into consideration how those choices will prevent chronic disease and build dietary patterns that promote long term health and well-being (Sorensen et al., 2012).

Figure 1. Conceptual research framework - Adapted from Sorensen et al. (2012)



1. Supplemented Food Regulations in the World

Supplemented Foods are a relatively recent type of food being regulated in the marketplaces around the world. The United States (2005), Australia (1989), New Zealand (2016), Japan (FOSHU in 1991, FNFC in 2001, FFC in 2015), and the European Union (2002), have each developed their own set of regulations on supplemented products.

The **United States** have specific requirements for what they call "Dietary supplements", regulated under the Dietary Supplement Health and Education Act (DSHEA) (FDA, 2018). These products are defined as "products intended to supplement the diet that bear or contain one or more of the following dietary ingredients: (1) a vitamin; (2) a mineral; (3) an herb or other botanical; (4) an amino acid; (5) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; and (6) a concentrate, metabolite, constituent, extract, or a combination of any ingredient mentioned above" (FDA, 2018). These products come in many forms: tablets, capsules, powders, energy bars and liquids (FDA, 2015). The FDA can only review dietary supplements for safety and effectiveness after

they are marketed. In terms of labelling, these products cannot be represented as a conventional food. Instead, their label must either contain the term "dietary supplement" or display the type of dietary ingredient followed by the word "supplement" (e.g. herbal supplement) (FDA, 2005). In addition to this requirement, the product must declare four other elements: (1) the net quantity; (2) the nutrition labeling; (3) the ingredient list; and (4) the name and place of business of the manufacturer, packer, or distributor (FDA, 2005). The term "dietary supplement" or its equivalent, as well as the net quantity, must be declared on the principal display panel (FDA, 2005). A "Supplemented Facts" panel must also appear on the label, listing the type and amount of the dietary ingredients, the serving size and the servings per container (if different from the net quantity) (FDA, 2005). This information is grouped in a box, with a large bold heading. A tabular or linear format may be used, depending on packaging size (FDA, 2005). If a warning is required, the information should be presented in a framed box, with the word "warning" as a heading, in uppercase letters (FDA, 2005). Research has shown that a high rate of American consumers use dietary supplements (60%) and they rely on the product label (43%) or on a health care professional (46%) to get information about the product (FDA, 2014). This survey also showed that 57% of consumers believe the government sets the manufacturing standards for vitamin and mineral supplements, and 27% believe they set them for herbs, botanicals, or supplements that are not vitamins or minerals (FDA, 2014). Warning messages on these products have lowered consumer perception of product safety and overall product evaluation, whereas efficacy perception was higher (Mason, Scammon, & Fang, 2007).

Japan has regulations for Foods for Specified Health Uses (FOSHU), Food with Nutrient Function Claims (FNFC) and Foods with Function Claims (FFC) (MHLW, 2018). FFC are "foods whose labels bear function claims based on scientific evidence." Evidence that supports the safety and effectiveness of the product are submitted to the Secretary-General of the Consumer Affairs Agency

before the product is marketed but individual pre-approval is not required (CAA, 2015). The front-of-pack label for FFC includes the text "Food with Function Claim" as well as the evidence-based claim. The recommended daily intake, any directions for use, warnings on risks of excessive consumptions, as well as specific notices must be listed on the back of the package (MHLW, 2018). The latter may warn people against using the product, such as those suffering from diseases, minors, pregnant women or those planning a pregnancy, or lactating women. FNFC are foods labeled with nutrient function claims specified by the Ministry of Health, Labour and Welfare (MHLW) (MHLW, 2018). There are 12 vitamin-related approved claims and 5 mineral-related approved claims. The claim, the recommended daily intake as well as the warning indication must be displayed on the label. A specific range for each vitamin and mineral is permitted (MHLW, 2018). Finally, FOSHU are foods containing ingredients with functions for health (MHLW, 2018). These products must be assessed for the safety and effectiveness of their functions for health and be approved by the MHLW before market appearance. If approved, the product would carry a Seal for FOSHU Approval. The purpose of FOSHU is the maintenance/promotion of health and/or the control of health conditions such as blood pressure (MHLW, 2018). A study on FOSHU labelling with undergraduates students from a Tokyo university showed that the vast majority of them were aware of the FOSHU system and around half of them were interested in products with a FOSHU seal (Ono & Ono, 2015). Products were perceived as healthier when the FOSHU seal was present, as well as those with a seal and health claims. Health claims independently did not have a positive impact on food evaluation. Another study was conducted with consumers, physicians and pharmacist on Foods with Function claims (Chiba, Sato, Kobayashi & Umegaki, 2017). Results showed that FFC were recognized by 81% of consumers, 93% of physicians and 98% of pharmacists. However, the percentage of understanding of FFC characteristics was not as high: only 16% of consumers, 23% of physicians, and 44% of pharmacists correctly understood the attributes unique to these foods (Chiba,

Sato, Kobayashi & Umegaki, 2017). Further research is needed on this topic.

Australia & New Zealand share a Food Standards Code (FSANZ, 2018). This code includes a sub-section for "Formulated supplementary sports foods." These products are defined as "a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals" (FSANZ, 2018). They may contain vitamins or minerals, amino acids and any other nutritive substance, such as L-carnitine, creatine, etc. These products have specific labelling requirements. The label must say "formulated supplementary sports food". This text must be legible and contrasting with the background of the label (FSANZ, 2018). The following guidance/cautionary labelling statements must also be present somewhere on the label: (1) the food is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet; (2) the food should be used with an appropriate physical training or exercise program; and (3) a warning that it is not suitable for children under 15 years of age or pregnant women and should only be used under medical or dietetic supervision (FSANZ, 2018). Any warning labels must be in a size of type of at least 1.5 mm for small packages and at least 3 mm for all other packages. In addition, the label must specify the recommended amount and frequency of intake as well as the recommended daily consumption (FSANZ, 2018). A research study investigated the use of Formulated Supplementary Sports Foods among consumers in Australia and New Zealand (FSANZ, 2010). "Sports Foods" and "Sports Drinks" were explored separately in order to understand how consumers define and differentiate the two. With Sports Foods, consumers relied on the back-of-pack information, notably the nutrition information panel, when purchasing a product for the first time (FSANZ, 2010). Their goal was to compare nutrient levels in order to get the most value for their money. For repeat purchases, they used the front-of-pack to look for information on flavour. When it came to advisory statements, many participants did not notice them on the label until it was pointed out during the discussion. Some were concerned that this information was not easy to find and recommended that it

should be in larger font and in a more prominent location so that parents are aware that these products are inappropriate for children. With Sports Drinks, participants reported use of the nutrition information panel to compare nutrient levels between products (FSANZ, 2010). However, they stated that their limited knowledge and the complexity of the label was frustrating and prevented them from interpreting the information properly. The label was reported as being "generally too confusing with too much writing, which was patronizing and frustrating" (FSANZ, 2010, page 42). Many words found on the FOP such as "scientific" and "isotonic" made them wary of drinking electrolyte drinks because they did not understand the meaning of these words. Advisory statements, such as "Not suitable for children under 15 years of age or pregnant women: should only be used under medical or dietetic supervision", were also reported as being too small and hidden. It was easy to miss them due to close proximity to other information such as the nutrition information panel. It was recommended to place this information in bigger font and in a more prominent area, such as the front-of-pack, to draw more attention to it. Finally, discussions with parents of children consuming sports drinks showed that requests for purchase of these products were made by children based on brand, colour and flavour (FSANZ, 2010). Most parents reported never looking at the back label of sports drinks because it's too confusing and is in too small of a print. Parents stated that they believed the scientific claims on the front-of-pack and trusted the recommendations made by sports coaches or athletes in advertisements. The advisory statements were identified as generally too small or difficult to see.

Australia also has a Therapeutic Goods Administration that regulates many therapeutic goods, including complimentary medicines (Health Direct, 2018). Complimentary medicines include vitamins, mineral and nutritional supplements, homeopathic, aromatherapy products and herbal medicines as well as traditional medicines (CMA, 2018). A food-medicine interface guidance tool was developed to help determine if a product should be regulated as a food or as a therapeutic good. However, no specific

labelling initiatives were taken to distinguish foods from complementary medicines (Australian Government, 2018).

New Zealand has established some identification requirements for supplemented foods (Ministry for Primary Industries, 2016). Supplemented foods are defined as "a product that is represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement" (Ministry for Primary Industries, 2016). Labelling requirements include having the words "supplemented food" in a prominent position on the label of every package as well as on all material advertising these foods. Specific placement of the information on the label is not specified. If there is a risk to a person in consuming more than an appropriate daily consumption of a supplemented food, the label on its package must specify the appropriate daily consumption and include an advisory statement to the effect that exceeding that daily consumption may cause harm. Specific placement of the information on the label is not specified. Specific restrictions also apply in relation to the addition of certain substances or exceeding certain amounts. In summary, the Food Standard for supplemented foods requires clear labelling on the identify SFs, in addition to BOP information to list the amount of supplemental ingredients and related cautions have a suggested benefit. Prior to the development of this Food Standard, a research study was conducted on food-type dietary supplement labelling (now called supplemented food) (FSANZ, 2003). The term "dietary supplement" (which was required on labels at the time) was not accessed or understood by consumers. Consumer awareness of the "dietary supplement" term was negatively impacted due to low prominence and "virtually invisible" placement of this information on the label (FSANZ, 2003). The font size of the "dietary supplement" term was smaller than the claims font size on the FOP and was subsequently considered to be of less importance by consumers. Suggested placement was on the front-of-pack, in a distinctively different format from the claims so that "dietary supplement"

term was not lost or dismissed with this information. In terms of understanding, participants were unsure if the term meant that the product contained dietary supplements or if the product itself was a dietary supplement. Consumers requested that products be clearly labelled with regards to supplements, including quantitative claims or statements on the type of supplemented ingredients. They also suggested the addition of "not intended for" or "not suitable for" as cautionary statements. An expectation among consumers was that the government would inform the public of any safety concerns associated with these foods and ensure proper public education about appropriate use of these foods (FSANZ, 2003). Unfortunately, no research study has been conducted to assess the effectiveness of the new regulated labelling tools in helping consumers distinguish these supplemented foods from conventional foods.

The **European Union** regulates "Food Supplements" as foods (EFSA, 2018). Food Supplements are "concentrated sources of nutrients (i.e. mineral and vitamins) or other substances with a nutritional or physiological effect." They are presented in a dose form, such as pills, tablets, capsules or liquids in measured doses. Although regulated as foods, they are found in a distinct format, similar to what is regulated as Natural Health Products in Canada (Government of Canada, 2016). The type of nutrients or ingredients that can be included in food supplements are vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts (EFSA, 2018). These products have specific requirements concerning the information that must be found on the product label: (1) the nature of the nutrients or substances in the product; (2) the recommended amount for daily consumption; (3) a warning not to exceed the stated recommended daily dose; (4) a statement emphasizing that the product should not be used as a substitute for a varied diet; and (5) a statement emphasizing that the products should be out of the reach of young children (EFSA, 2018). These specifications can be found under Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 (EUR-Lex, 2002). The placement of the information on the label is not specified in the regulations. Research has been

conducted to assess the safety of different ingredients included in food supplements; however, no research was conducted to evaluate consumer access and understanding of the specific labelling information of food supplements.

In **Canada**, a guidance document was published by Health Canada in 2016 to define the term "Supplemented Food", specify permitted maximum levels for certain vitamins and minerals as well as set out required labelling and advertising requirements (Government of Canada, 2016). Other information is also included in the guidance document. In terms of labelling, specific cautionary labelling text must be included on products that exceed the stated amount of a certain vitamin and mineral. Examples include "Not intended for children", "For adults only" and/or "If you take a daily supplement, you may be getting too much vitamins or minerals by consuming this product." In addition, the common name of a standardized food must indicate how the food differs from the standard. For example, cereal has a standard of identity in the regulations (Government of Canada, 2018). This means that cereals need to adhere to specific requirements set out in the regulations. If a cereal is supplemented, the common name must indicate how it differs from the standard (i.e. how it differs from what is specified in the regulations). An example would be the words "cereal supplemented with Vitamin B_6" on the front panel of a cereal box. Finally, if a product is supplemented with nutrients listed in the NFt, the total amount of the nutrient (i.e. natural amount in the food and supplemented amount) must be listed in absolute value and percent of daily value, in the NFt. Any of these requirements should meet the same requirements for legibility and prominence as the NFt to ensure consistency between all regulated labelling information (Government of Canada, 2016).

Various regulations and labelling strategies for "supplemented foods" have been adopted across the world. The variety of these supplement-type products are defined and dealt with differently depending on the country. Although consumer awareness and recognition of the labelling initiatives for

these products is high for some of these countries, consumer understanding of the nature of these products, how they differ from conventional foods, and why they require cautionary labelling or directions for use appears to be lacking. One common theme across the globe is the need for clear labelling, on both the FOP and BOP, to ensure that consumers can distinguish these types of products from conventional foods, identify the nature of the supplemental ingredients, and be able to evaluate any cautionary labelling or directions for use so that they can make an informed decision as to the appropriate use of these foods. Given these requirements, it is important to investigate how consumers interact with labels, and more specifically, their awareness, understanding and appraisal of available labelling information in order to ensure that the developed SF labelling strategies facilitate appropriate consumer use of these products.

2. Consumer Awareness of Supplemented Foods

The first consumer competency of food based decision making is the ability to seek, find and obtain appropriate food and nutrition information. This includes but is not limited to food labelling on supplemented foods. The ability to easily identify and distinguish supplemented foods from conventional foods is important because, although there is a long history of foods on the market that have been vitamin/mineral enriched or fortified according to regulated measures, foods supplemented with certain herbals or bioactives have a limited history of safe use (Government of Canada, 2016). Some might not be appropriate for everyone and/or need conditions or directions of use (e.g. products with caffeine are not recommended for pregnant or breastfeeding women or people sensitive to caffeine). Some consumers might perceive the addition of vitamins and minerals to foods of otherwise poor nutritional value as an ‘added bonus’ (Health Canada, 2004). If such foods are perceived as healthier and are found in a variety of packaged-foods, there is a potential risk of nutrient imbalances and/or high intakes approaching or exceeding tolerable upper intake levels for vitamins and minerals (Dietitians of Canada,

2009; Health Canada, 2004). There is also the potential for inappropriate use of these products if they lack labelling features that clearly distinguish them from other foods products. This is particularly important with foods that are unhealthy in other respects. If consumers perceive these foods to be healthier without considering their other nutritional attributes, SFs have the potential to lead to unhealthy dietary changes. This has been observed with consumer attitudes towards fortified foods: consumers expressed interest in consuming fortified foods and increasing their consumption of certain foods if they became fortified, such as salty snacks, soft drinks, fruit juices and bars (Kalergis & MacDonald, 2009). This reinforces the importance of labelling approaches that enable consumers to distinguish these foods from conventional products, identify the nature of the supplemental ingredients and understand their directions and/or cautions for use to make an informed food choice.

Previous consumer research to determine labelling approaches that would help consumers identify foods with medicinal ingredients, now called "Supplemented Foods", indicated that a front-of-pack identifier for SFs in addition to other back-of-pack nutrition labelling information would be useful (Health Canada, 2010). Findings from these consumer discussion groups highlighted consumer preferences for a product identifier on the FOP of foods, a tabular/framed format with a distinct heading to present all the necessary information, and a standard caution statement on all supplemented foods.

3. Consumer Understanding of Supplemented Foods

Understanding nutrition information is crucial when making food based decisions in order to evaluate food choices in the context of one's dietary goals or needs. Understanding information requires motivation, nutrition knowledge and a certain degree of thought i.e. cognitive processing (Grunert, Wills, et al., 2010; Miller & Cassady, 2012). It also requires literacy and numeracy skills to be able to read and comprehend the information (Rothman et al., 2006). Consumers with poor literacy and numeracy skills have been shown to perform incorrect calculations using the serving size or the nutrients

on the NFt, unlike those with higher skill levels (Rothman et al., 2006). The use of graphic presentations in the NFt, as opposed to only words and numbers, appeared to help consumers with lower levels of literacy to assess the healthiness of foods (Viswanathan et al, 2009). Lack of understanding of the more detailed nutrition information on the back of food packages might push consumers to rely on simpler pieces of information, found on the FOP, that do not necessarily present the whole picture (Scheibehenne et al., 2007). If consumers incorrectly believe they understood the information, this may lead to a false overall evaluation of the product (Geyskens, Pandelaere, Dewitte, & Warlop, 2007; Grunert, Wills, et al., 2010; Craig Andrews et al., 2011; Malam et al., 2009).

Recent regulatory driven research conducted in Australia has integrated the moderating effect of consumers' individual prose literacy and numeracy skills into their food labelling research with Australian consumers (Australian Government, 2013). This evaluation of the recently proposed *Health Star Rating* FOP food labelling system identified differences between consumers of medium to high literacy and those at lower literacy. The latter group preferred the stars element of the scheme and the word "rating" because the message is easy to understand and it makes them more conscious of what they are eating compared to those of higher levels, who questioned the accuracy of the scheme and also needed numerical values to increase credibility of the scheme. These differences highlight the importance of assessing literacy levels to ensure that the identified labelling approaches are salient to those who are the most disadvantaged by marginal literacy. From a supplemented food perspective, findings from this study showcase the need to include text with symbol-based labels to promote better symbol understanding and to include quantitative labelling for the supplemental ingredients to understand and evaluate the food.

With the perceived complexity and misunderstanding of current labelling tools (i.e. NFt, LOI, etc.), prospective labelling tools specific to SFs (i.e. the supplemental ingredients and the

directions/caution labelling) need to be accessible and easy to interpret and understand. It is important to use wording and measures that are easily understood and avoid complicated and confusing terminology (Heath Canada, 2010). Education will play a key role in labelling access, understanding and appraisal to make a food choice.

4. Consumer Appraisal of Supplemented Foods

The third consumer competency with food-based decision making is the ability to interpret, filter, judge and evaluate the food and nutrition information that has been accessed and understood (Sorensen et al., 2012). Of importance here is the ability to evaluate the food and place its use in the context of one's own dietary needs and goals.

Appraisal is a context driven dimension, being highly influenced by the consumer's own set of priorities and understanding of the information accessed (Miller & Cassady, 2012; Turner, Skubisz, Pandya, Silverman, & Austin, 2014). With consumers exposed to a variety of labelling information, both on FOP and BOP, evaluating the information requires much cognitive effort and motivation (Grunert, Wills, et al., 2010; Miller & Cassady, 2012). It has been suggested that consumers have trouble translating BOP regulated nutrition information into practical guidance and interpreting how the different nutrients play a role in their diet (Cowburn & Stockley, 2005; Temple & Fraser, 2014). In the case of supplemented foods, the BOP may include quantitative labelling of the supplemental ingredients as well as cautionary/directions for use labelling to ensure appropriate use of the product. Consumers need to be able to appropriately evaluate this label information in the context of their own diet in order to appropriately use these products. This underlines the importance of supplemented food labelling so that all consumers, when appropriate, can translate the information into practical guidance for themselves and their family members.

5. Scope of this Thesis

The objectives of this research are to determine the key components of a labelling approach to ensure that consumers of varying health literacy levels can:

1- Identify and distinguish SFs from other foods

2- Identify the type and amount of supplemental ingredients

3- Understand any directions or caution associated with particular SF use

Chapter III
Materials and Methods

Design

This qualitative study utilized individual interviews and discussion groups to assess consumer competencies with current and tested labelling information for supplemented foods in Canada. The use of interviews followed by discussion groups helped identify salient pieces of information on an individual level, which were confirmed in discussion groups, where participants had a set of packages and needed to determine which one is supplemented, what it is supplemented with and if there is any caution for use.

Participant Recruitment

We targeted three sub-groups of consumers living in the National Capital Region of Canada: parents with children living at home under the age of 18, adults over the age of 55 and physically active adults over the age of 18. Parents are the main food decision makers for their children and have a particular interest in the nutritional health of their family (West & Larue, 2004). Therefore, they may have specific interests in the benefits and limitations of using SFs. Adults over 55 years of age may have particular interest in the purported health benefits of some SFs for health promotion and management of chronic diseases (Urala & Lähteenmäki, 2007). Physically active adults over 18 years of age may have a particular interest in the purported weight management, mental health and performance benefits of specific SFs (McDowall, 2007; Wiens, Erdman, Stadnyk, & Parnell, 2014).

A purposive sampling strategy was used to recruit a convenience sample of English and French speaking participants of varying levels of health literacy (as assessed by the Newest Vital Sign ©). The Newest Vital Sign© (NVS) is a health literacy assessment tool recently adapted for use in Canada (Mansfield, Wahba, Gillis, Weiss, & L'Abbé, 2018) and validated for use with older adults (Patel et al.,

2011), youths (Linnebur & Linnebur, 2016), parents and children (Driessnack, Chung, Perkhounkova, & Hein, 2014), and people with chronic diseases (Bailey et al., 2014). The NVS assesses a person's likelihood of limited, marginal, or adequate health literacy. This six-question tool assesses prose (text) and numeracy skills using a nutrition facts table on a container of ice-cream. Based on the number of correct answers, the participant is categorized as having a "high likelihood" of low health literacy (score 0-1), "possible" low health literacy (score 2-3), or "adequate" health literacy (score 4-6). For the purpose of this study, we assigned "at risk of marginal or limited health literacy" for scores below 4 and "adequate health literacy" for scores between 4 and 6.

We consulted with local community health promoters and allied health professionals to identify local groups that meet the participant profiles of interest. We partnered with a Community Health Center (Ottawa, Ontario) to access community groups and find interested participants. French and English physical activity groups for seniors at community centers in a range of socio-demographic areas, as well as chronic disease management sessions, were targeted to reach seniors of different literacy levels. Local gyms, university gyms and specialized exercise groups (e.g. CrossFit) were targeted to reach physically active individuals of various ages and levels of physical activity. Waiting areas at sports fields during youth sporting events, parent playgroups in a range of socio-demographic areas as well chronic disease management sessions were targeted to reach parents with children of different ages. The interview or the discussion group was held in the area where the person was recruited or in another location convenient to them.

At each location (e.g. community centers, gathering rooms in senior homes, local coffee shops and restaurants, grocery store rental rooms, etc.), the moderator of the group introduced one of the co-investigators (RW), who provided a brief description of the project to the whole group and took note of

the interested participants' contact information. Federal, provincial and municipal government employees, university employees, individuals in advertising, public relations, communications, marketing research industries, and media representatives, as well as those working in the public health/medical sector and food manufacturing were excluded from this research. Informed consent was obtained from all potential participants. Both Health Canada's and the University of Ottawa's Research Ethics Boards approved the study.

Data Collection

This consumer research consists of two distinct studies. In Study A, a total of 31 individual interviews, 19 in English and 12 in French, lasting between 20-30 minutes, were conducted with consumers of varying health literacy levels. In Study B, 8 discussion groups, one in French and seven in English, each made up of 5-8 individuals, lasting between 40 – 60 minutes, were conducted with consumers of varying health literacy levels. Distinct discussion groups were carried out for consumers of adequate literacy separately from consumers at risk of marginal literacy. The interviews and discussion groups were held in private meeting rooms at locations closest and most convenient to the participants (e.g. local community centers) and were digitally audio-recorded with the permission of the participants.

The purpose of the interviews was to obtain feedback from consumers on their awareness, understanding and appraisal of the different labelling options presented to them and to determine which ones enable them to quickly and easily identify supplemented foods, their supplemental ingredients and any directions or caution for use. A moderator's guide was developed to ensure that each interview and discussion group was conducted in a similar fashion and to clarify the topics and questions to be discussed. Additional probing questions were identified a-priori and used, when needed, at the discretion of the moderator. Pilot interviews (n = 2) and one discussion group (6 participants) were conducted to

refine and enhance the moderator guides.

Labelling Tools

The labelling tools were developed based on findings from previous consumer research conducted by Health Canada on Natural Health Products in food formats, now called "Supplemented Foods" (Health Canada, 2010).

SF labelling tools consisted of both FOP and BOP variants of (1) an FOP product identifier; (2) a BOP supplemental ingredients label, and (3) BOP cautionary labelling (Appendix A: interview labelling tools).

All labelling tools were integrated onto mock-packages of cereals, beverages and bars. These three food products were chosen for a number of reasons: (1) many of the foods currently on the market and recognized as supplemented foods by Health Canada fit in these three food categories (Government of Canada, 2014, 2016); (2) these food categories contain an assortment of choices of varying levels of healthiness, with the latter possibly impacting consumers' perception and understanding of the SF labelling information; and (3) by using varying sizes of food packages, from large (cereal) to small (bar), we can determine the hierarchy (amount, size and placement) of label information that participants need to identify and distinguish a supplemented food. This approach was proposed to facilitate participants' determination of the most and the least amount of information they need to identify a supplemented food, to understand the type and amount of supplemental ingredients, and to identify and acknowledge any directions or caution for use. For the discussion groups, each mock-up was also labelled with other regulated labelling information (see table 1).

Table 1: Discussion Group Mock-up Labelling

Required Labelling for all mock-ups	Food package attributes
Base food category (common name)	Cereal Bar Beverage
Brand Name and Stock Food Image	"photo enlarged + suggested serving" has to be within proximity of stock image of stock image on PDP
Front of Pack (FOP) Claims	Regulated health/nutrient content claim Marketing claim
Regulated Nutrition Labelling Size varies depending upon principle display panel and available display space on FOP (- UPC code space and folding overlap)	Common name of food on PDP Net weight (bolded on FOP) Nutrition Facts table (NFt on BOP) List of ingredients (LOI) Allergen Labelling (If Required on BOP) Place of Business (City/Postal Code) Recycling logo (anywhere) UPC Bar Code (anywhere) BEST BEFORE with Date (anywhere)

Interviews

One of two bilingual co-researchers (EM, RW) conducted the individual interviews, beginning with the NVS screening tool for health literacy assessment, which helped facilitate communication with each participant. The moderator's guide was developed using plain language principles. Slower speech rate, pausing at the end of each sentence and informing the participants that all information could be repeated as needed was particularly adhered to with participants at risk of marginal health literacy.

Once the NVS was completed, the interviewer gave Health Canada's definition of a supplemented food as follows:

> *We have new foods and drinks on the market, with "Supplemental Ingredients." These supplemental ingredients could be: (1) herbals such as ginseng or guarana (e.g. cereal with ginseng or margarine with plant sterols that help lower cholesterol); (2) bioactive ingredients such as caffeine (e.g. energy drinks); (3) added vitamins and minerals as seen in vitamin mineral water and bars with vitamins. Health Canada calls these foods "Supplemented Foods."*

To help participants better understand this complex definition, the interviewer gave specific examples for each type of supplemental ingredient, showed real examples of supplemented food packages and highlighted the supplemental ingredient(s) in each SF. The interviewee was given an opportunity to ask any questions about the food, food packaging, and label information. Once all questions were answered, each participant was given a sample sheet containing 6 various product identifier designs for use on supplemented food packages. The first design was an "S" in a circle shape; the second was an "S" in an arrow shape, and the third was an "S" in a square shape. For each shape, the participant saw two design versions, with and without the wording "supplemented/supplémenté" as part of the design. The participant was asked to rank the different product identifiers from their most preferred to least preferred front of pack labelling identifier for supplemented foods. Probing on the ranking was done by the interviewer in order to understand the reasoning behind the choices (which one would be easy to find and understand). This ranking exercise was followed by a set of three tasks that involved choosing and placing various pieces of information on the different packages. First, a cereal box was given to the participant and he was asked to place his preferred supplemented product identifier on the package. Second, different designs and sizes of the supplemental ingredients information were shown to the participant and he had to place his preferred choice somewhere on the cereal box. Third, different designs and sizes of the caution statement were given to the participant and he had to place his preferred choice somewhere on the package. Probing was done to understand the reasoning behind the design, size and location selected for each piece of labelling information. The same three tasks were repeated with a juice bottle and a bar (Appendix B: Semi-structured interview guide).

Discussion Groups

One of two bilingual co-researchers (EM, RW) moderated each discussion group, with the other taking notes. Preliminary discussion groups were co-moderated to ensure that both moderators were

familiar with the questioning and comfortable with probing to gain further insights on participants' interaction with labelling information. Subsequent discussion groups (n=8) were moderated by one co-researcher while the other took notes and intervened at a few occasions to clarify/ensure understanding of participants' responses.

Each discussion group began with an ice breaker to get the participants comfortable with one another. They were asked to state their name and their favorite food. This was followed by the moderator giving a general definition of supplemented foods. The definition given to participants was the same as the one used in the individual interviews (found above). The participants were also shown real supplemented foods (e.g. vitamin water, bar, cereal) and the moderator specified the supplemental ingredient(s) in each product. Participants were given the opportunity to ask any questions or request clarifications about the SF definition. Afterwards, the group was divided into sub-groups of 2-3 participants, each group receiving a set of packages (3 cereals, 3 beverages or 3 bars). Each set of packages included one conventional food, one supplemented food with the current labelling strategy and another supplemented food with the tested labelling strategy. The conventional food mock-up was a non-supplemented food. The supplemented food mock-up with the *tested* labelling strategy involved a product identifier with the wording "supplemented/supplémenté" on the FOP in a clutter-free area, a supplemented box with a distinct "Supplemented" heading on the side or BOP, and a caution statement with a distinct "caution" heading, when applicable, adjacent to or below the supplemental ingredients box. The design and location of these labelling pieces was based on the findings from the individual interviews. The supplemented food mock-up with the *current* labelling strategy included a caution statement, where applicable, with no distinct "caution" heading and not within an outlined box. In addition, cereal mock-ups with the *current* labelling strategy included the wording "supplemented with [enumerate the supplemental ingredients]" near the common name of the food. (Appendix C: discussion

group mock-packages).

Each sub-group had to determine which, if any, of the foods they received fall under the category of supplemented foods. Participants were given enough time to interact with the food package. The moderator observed the group and used consumer cues to determine if they were done interacting with the label (e.g. participants start looking at the moderator, start deviating from the topic within their sub-group, etc.). The moderator brought the group back together to discuss whether the tested labelling tool was easy to find compared with the current labelling tool. Sub-groups then exchanged sets of packages with each other so that they could interact with a different food category in the next task, which involved identifying the type and amount of supplemental ingredients. Once this task was completed, they exchanged sets of packages again for the third and final task, consisting of identifying any cautionary labelling on the food. Probing questions were used during each task to assess access, understanding and appraisal of the pieces of labelling information used to answer the questions (see Appendix D: Semi-structured discussion group guide for the exact probing questions used). Even when incorrect pieces of information were used to answer questions, probing was done to understand the participants' thought process and identify gaps in understanding that may be addressed through education (Appendix D: Semi-structured discussion group guide).

Compensation

Participants were given a $25 food voucher to use at a local grocery store after completing the interview or the discussion group. If the participant needed to take the bus to get to and from the interview or the discussion group, they were given bus tickets to cover their transportation costs. Also, reimbursement up to a maximum of $15 was provided if there was a need to pay for a taxi, parking or child-care to be able to take part in the study. Proof of payment was required in order to get reimbursed.

Data Analysis

An a-priori content analysis codebook was created based on our research framework (Appendix E: Codebook). This codebook was used to conduct a thematic content analysis of each interview and discussion group exploring the themes of consumer access, understanding, and appraisal of both current and tested labelling information for supplemented foods. Interview and discussion group texts were coded independently by the co-researchers (EM, RW) using NVivo Qualitative Software Tool (NVivo, 2018). Afterwards, co-researchers discussed their findings and discussed disagreements in coding in order to come to a clearer understanding of the coded information. Participants' words were used to summarize the key themes and sub-themes.

Chapter IV
Findings

Interviews – Task 1: Identify supplemented foods using a product identifier

Figure 2. Salient Product Identifier

Access/Awareness

Findings for Task 1 were similar across literacy groups. Awareness of the circular product identifier was most prevalent among participants because the stylized "S" is recognizable as a letter and the text "Supplemented" is readable, compared to the other styles of product identifiers:

"I picked the biggest one with the round circle around it because the S looks like an S and not a stylized design"

"[The S in a square] looks like a roadmap. It looks like a snake and a road."

"Here they are a little bit more condensed [arrow and square]. It's not as visible. There is more space between the letters [in the circle]"

Black and white was generally identified as sufficient for quick access, as long as the symbol is located in a clear and clutter-free location. Participants also commented on the potential for the addition of color to the symbol (such as red) to make it stand out and to highlight its importance. Another factor for improved access is placement near the brand name of the food or the front-of-pack claims in order to read all information at one glance.

"So on the left of the warning [the claim "High caffeine content"] *and close to the name of the product* [brand name]*...In the upper right corner of Crave* […] *So my first look reads everything that's important. I don't have to search."*

The size of the symbol was an important accessibility factor, particularly for participants of

marginal health literacy: large product identifier is easily located on the packaging.

Understanding

Inclusion of the word "Supplemented" as part of the product identifier along with the stylized "S" enabled participants to understand the meaning of the "S". Some participants mentioned that with time, they may learn to associate "S" with a supplemented food. However, for the time being, wording was necessary for them to understand the product identifier.

> *"As a first time user the wording is important but once I got used to the labels then it wouldn't matter. But to see that writing first say if I didn't know anything* [about these foods] *and I was walking into a store and I see it written it's going to draw my attention to it […]"*

The table below (Table 2) highlights key quotes for every theme. The participant's health literacy level is specified in brackets at the end of every quote.

Interviews

Table 2. Interviews – Task 1: Product Identifier

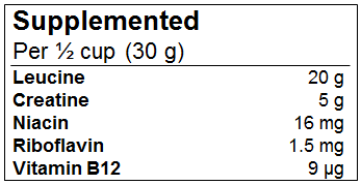
Key Themes	Sub-Themes and Quotes	
	Labelling Designs	**Packaging Attributes**
   **Accessibility and Awareness**   	**Legibility** *"the S here [in the circle], you should have the S inside, completely, like this one, where the S is inside completely [in the arrow]. Here, it's cut off at the bottom"* *(adequate literacy)* *"I picked the biggest one with the round circle around it because the S looks like an S and not a stylized design"* *(adequate literacy)* "[The S in a square] *looks like a roadmap. It looks like a snake and a road."* *(adequate literacy)* *"Here they are a little bit more condensed* [arrow and square]. *It's not as visible. There is more space between the letters* [in the circle]" *(adequate literacy)* *"The round Product Identifier with the wording as I was looking at it straight "supplemented" instead of kind of at an angle* [in the arrow] *although the square one is* [straight] *too. But I just like the look of the round label."* *(adequate literacy)* *"I just didn't like it [S in square]. I got lost in the design"* *(marginal literacy)* *"It looks like a stop sign. I don't know, it looks like a road sign or something [square with no wording]"* *(marginal literacy)* *"It's clear, it's in white. The S is nice and big [circle with wording, biggest size], supplemented is written in there [the circular symbol]* *(marginal literacy)*	**Clutter-free location** *"Probably place it up on the top left above the logo, just cause that looks like an open white space where it could be clearly seen."* *(adequate literacy)* *"Bottom left hand corner because there is nothing else there. If you put it up here, it's going to be confusing with this, If you put it over the label, you won't be able to read the label. Here, it's by itself in a corner, it's visible."* *(marginal literacy)* *"Since it's something so important, the reading starts from left to right so we start with this [the symbol] by saying it's supplemented"* *(marginal literacy)* *"On the bottom right of the FOP. It seems to have a lot of clear space on the bottom and visually my eye is drawn"* *(marginal literacy)* **Proximity to Other Regulated Information** *"So on the left of the warning* [the claim "High caffeine content"] *and close to the name of the product* [brand name]*...In the upper right corner of Crave* […] *So my first look reads everything that's important. I don't have to search."* *(adequate literacy)* *"Then what I would do is put the "supplemented" piece where it says "contains" whatever the item is going to be contained. I would try to keep those two together"* *(marginal literacy)*

	Readability *"The first one which actually has the written and the S symbol. It's a circular shape. It's clear and it's readable, I have a visual and I can also read it"* *(adequate literacy)* *"I am reading what it says "supplemented". I can read what they say. The 1st three are pretty good* [the three with wording]. *The last 3 are terrible* [the three symbols with no wording]. *So what I am picking here is the one I can read the easiest. It has the biggest writing* [circle with wording]." *(adequate literacy)* *"1st three* [identifier with symbol and word] *because I think it is much clearer rather than just having the symbol, to actually have the word supplemented in my top three picks."* *(marginal literacy)* *"It means nothing to me, it could mean anything [S with no wording]"* *(marginal literacy)* *"Having the word supplemented and the symbol is a clearer message in the grocery store when you are bombarded with all the visual messages that you get"* *(marginal literacy)* **Contrast** **Black and White** *"The white S with the black background. You can clearly see "supplemented."* *(adequate literacy)* *"The white S with the black background. You can clearly see "supplemented". I like the circle better, less black, seems to stand out a little bit more to me. The "S" supplemented seems to draw/stands out to me."* *(adequate literacy)* *"I stuck it there because I got the white background here, with the black. My eye automatically goes to it."* *(marginal literacy)* **Color** *"And I think it* [product identifier] *should be in red or some bright stand up color* […] *At least, there should be some red in it, because black and white doesn't stand out."* *(adequate literacy)* *"First of all, these labels [caution], if they are that serious, they should be red. They should be red and black. Red is attention grabber and you*	

	go right to that because you say what's this, it's in red. I think it should be red and somewhere here." *(marginal literacy)*	
Understanding	**Recognition** *"I like the ones that actually say supplemented cause otherwise* […] *to me an S says nothing"* *(adequate literacy)* *"As a first time user the wording is important but once I got used to the labels then it wouldn't matter. But to see that writing first say if I didn't know anything* [about these foods] *and I was walking into a store and I see it written it's going to draw my attention to it. If it didn't* [have the words supplemented on the label] *then I probably wouldn't notice anything, unless somebody told me about the product and I knew beforehand and then I would spot the label"* *(adequate literacy)* *"Because of the S and because it's written, I find it clear, especially because […] the symbol by itself, not sure if I would understand"* *(marginal literacy).*	**Proximity to other regulated information** *"I placed it, to the right, a bit under the green symbol [the high caffeine content claim]. Because the main supplemented is caffeine and it's directly under the caffeine, to say it's mostly supplemented with caffeine"* *(adequate literacy)* *"Under the green label that says "high caffeine content helps maintain physical alertness" cause then you see there is "supplemented" and what it's supplemented with […] It's all concentrated in one area."* *(marginal literacy)* *"I actually think I would like the product identifier next to the claim – it separates that claim – so that I know that the claim is related to the supplemented* [ingredients]*"* *(adequate literacy)* *"I would place the SF symbol on the bottom left of the FOP and link it to the calcium and vit D claim as I assume that they have been added to the beverage."* *(adequate literacy)*

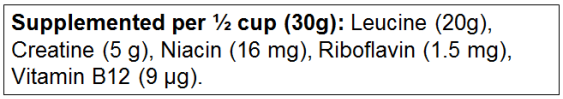
Interviews - Task 2: Type and amount of Supplemental Ingredients

Figure 3. Salient Supplemental Ingredients Box



Supplemented	
Per ½ cup (30 g)	
Leucine	20 g
Creatine	5 g
Niacin	16 mg
Riboflavin	1.5 mg
Vitamin B12	9 µg

Tabular Format



Supplemented per ½ cup (30g): Leucine (20g), Creatine (5 g), Niacin (16 mg), Riboflavin (1.5 mg), Vitamin B12 (9 µg).

Linear Format

Access/Awareness

Participants noticed the tabular format of the supplemental ingredients box (see above). Key to this awareness was the recognition of its similar look and feel to other familiar nutritional information (i.e. the nutrition facts table), and the presence of a distinct heading which drew their attention. In addition, this format was easier to read compared with a linear format that involved many commas and brackets in a continuous line. Placement of this information on either the FOP or the BOP was reported accessible; however, placement on the BOP, near the NFt, helped participants to see all nutritional information in one glance. Some participants at risk of marginal health literacy placed the supplemental ingredients information on the front-of-pack, near the product identifier, to know that the food is supplemented and what it's supplemented with.

"This is much better [tabular format]. *Well you have to, like here, you just read each line, and it's very separate and clear* [the box]. *Whereas here, you have to go across and pay attention to the comas and the brackets and so you have to deconstruct the sentence. Like you deconstruct a sentence when you read, but it's not English right? It's all short hand. Sort of like a combination of math and English whereas here* [the box], *it's clear and bold."*

For the large, portrait-type packaging (i.e. cereal box), participants chose the tabular format of the supplemental ingredients box.

"Because it's clearer [tabular format], *we are also more used to it. We are used to seeing the nutrition elements in rows and tables like this, with the numbers to the right, the grams, the percentages. We are used to it."*

For the linear, landscape-type packaging (i.e. bar), participants chose the linear format of the supplemental ingredients box. Considering its significantly smaller packaging size, participants opted for

this format because everything is done in length on the label and it is easier to follow along in a line.

"Because of the format of the product [the bar]*, because everything is done in length, so it's easier to put it on the horizontal than the vertical, but for sure I stick with my idea that it's clearer in this format* [tabular format]. *But, for a bar, it's easier to read like this since it's done in length"*

Understanding

Participants wanted to see the percent daily value (%DV) in addition to the milligram labelling in the supplemental ingredients box, as found in the NFt. This would help them better translate the meaning of the information:

"We need mg in NFt as well as the %DV and the same for the SI box. Without that it gives me no information. 6 mg could be a little or it could be a lot, I don't know. I need a translation into %DV."

"If we use the recommended daily amount [in the NFt] *for a guide, that would be a lot easier and it would help more as a consumer compared to something that says supplemented and amounts that say nothing."*

The meaning behind the amount listed in the supplemented box was understood in some cases. Participants recognized that the NFt contains the total amount of the nutrient in a food vs the supplemented box that contains only the supplemented amount of that nutrient.

"So now, I am confused right, you say this is supplemented so now I have to do the subtraction between this and that [the NFt and the SBox]. *So maybe it might be useful to say that it's been supplemented right, these are the parts that have already been supplemented.* […] *because then I would know this amount is being supplemented but I would need to be educated that just the supplemented has already been added into these ones* [the numbers in the NFt]. *I mean by looking at 200%, I mean, you also make the assumption that it's been supplemented. But if you don't really understand it, there is a chance that you would be confused by that."*

Appraisal

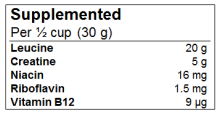
Certain types of supplemental ingredients found on the label pushed participants to evaluate the food it in the context of their own diet.

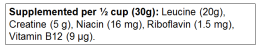
"You are telling me that these are supplements that are good for me. I seem to remember that Leucine is not good with medication that I take, I have to be careful."

The table below (Table 3) highlights key quotes for every theme. The participant's health literacy level is specified in brackets at the end of every quote.

Table 3. Interviews – Task 2: Type and Amount of Supplemental Ingredients

Key Themes	Key Themes and Quotes	
	Labelling Designs	**Packaging Attributes**
Accessibility and Awareness	**Legibility** **Tabular format** *"Because it's clearer* [tabular format]. *We are also more used to it. We are used to seeing the nutrition elements in rows and tables like this, with the numbers to the right, the grams, the percentages. We are used to it."* *(adequate literacy)* *"The box [is easier]. I can just quickly look and easy the order. Whereas [the linear format], I have to read across the list. [The box] it's clearer".* *(marginal literacy)* *"This is much better* [tabular format]. *Well you have to, like here, you just read each line, and it's very separate and clear* [the box]. *Whereas here, you have to go across and pay attention to the comas and the brackets and so you have to deconstruct the sentence. Like you deconstruct a sentence when you read, but it's not English right? It's all short hand. Sort of like a combination of math and English whereas here* [the box], *it's clear and bold."* *(adequate literacy)* *"The box. Easy to read. I don't have to have a curser and to go with the finger. They are listed from top to bottom"* *(adequate literacy)* *"I would go with the supplemented box. Because it's more readable. Read across this way. You know supplement, ½ cup, it's got leucine 20g, vitamin B12. Then here you got this in brackets, this in brackets, this in brackets, this in brackets. So it's too much to take in with the eyes. But this one here, right across."* *(marginal literacy)* **Linear format** *"Because of the format of the product* [the bar]. *Because everything is done in length, so it's easier to put it on the horizontal than the vertical, but for sure I stick with my idea that it's clearer in this format* [tabular format]. *But, for a bar, it's easier to read like this since it's done in length."* *(adequate literacy)*	**Proximity to other regulated information** *"Because when I look for the nutrition facts on the label, I know that I will look on the side of the box. So I placed it on the same place, to avoid having to turn the box to look."* *(marginal literacy)* *"I would put it, so there is the NFt, the ingredients and then the supplemented. So I would put it on the side, under the ingredients"* *(adequate literacy)* *"when you're looking for nutrition information, you like flip to the side. Yah, you flip to the side with I guess in whichever language the nutrition information you read. So if it's right underneath all the nutrition facts and the ingredients, that, it'd be most easily to see"* *(adequate literacy)* *"I have everything on the left, so top left corner; I have the green leaf that says "high caffeine content". To the right of the leaf, I have the larger symbol that says it's supplemented and underneath the little leaf, I have the supplemented items. I like to keep them all together so that I know that those are the items that have been supplemented."* *(marginal literacy)*



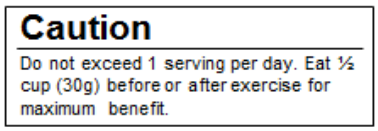


	"[…] I can get this one [the linear format] mixed up with the ingredients […] the problem is you get it mixed up with the ingredients […] But this [the tabular format] is just too hard to fit on the packaging. Like that just looks ridiculous, for one, unless you kind of stuck it over here, on the side" *(marginal literacy)* **Recognition** *"Just cause it's more like the information for the nutrition facts. Instead of kind of like listing the ingredients…So yah, it lets you know what the amount that's in each thing. It's kind of more neatly organized"* *(adequate literacy)* *"This one is simpler [the tabular format]. Well again, it's just super easy to read […] I go right across. And you know, partly it also is historical compared to the nutrition label as it is now, it's similar"* *(marginal literacy)*	
Understanding	**Confusion with the Nutrition Facts Table Principles and Information** *"If we use the recommended daily amount* [in the NFt] *for a guide, that would be a lot easier and it would help more as a consumer compared to something that says supplemented and amounts that say nothing."* *(marginal literacy)* *"We need mg in NFt as well as the %DV and the same for the SI box. Without that it gives me no information. 6 mg could be a little or it could be a lot, I don't know. I need a translation into %DV."* *(adequate literacy)* *"So now, I am confused right, you say this is supplemented so now I have to do the subtraction between this and that* [the NFt and the SBox]. *So maybe it might be useful to say that it's been supplemented right, these are the parts that have already been supplemented.* […] *because then I would know this amount is being supplemented but I would need to be educated that just the supplemented has already been added into these ones* [the numbers in the NFt]. *I mean by looking at 200%, I mean, you also make the assumption that it's been*	

	supplemented. But if you don't really understand it, there is a chance that you would be confused by that." *(marginal literacy)*	
Appraisal	*"I don't know, am I supposed to have 225 mg of vitamin C or not? I don't know, people don't know that right off the top of their head […] So if they are warning you [in the caution box] that with this amount of vitamins, you should probably either drink this or have a multi [multivitamin], don't do both. And I thought that was pretty good personally."* *(adequate literacy)* *"You are telling me that these are supplements that are good for me. I seem to remember that Leucine is not good with medication that I take, I have to be careful."* *(marginal literacy)*	

Interviews – Task 3: Caution statement

Figure 4. Salient Caution Box



Access/Awareness

Factors for improved awareness or noticeability of the caution statement included a separate distinct heading with the words "Caution/Attention" and placement of the cautionary labelling below the supplemental ingredients box.

"Because I want everything to be written at the same place. I don't have time, when I am grocery shopping, to look what's important to read. It all has to be put together."

Participants also mentioned the possibility of highlighting the caution on the front-of-pack. This was particularly important among participants at risk of marginal/limited health literacy. Many of those participants felt the caution box was too wordy and they would have no time to read all this information. They suggested using the word "caution" with a symbol, on the front-of-pack, to highlight the importance of this cautionary labelling to all consumers, but in particular to those that might not have the time/motivation to access the BOP information. Some suggested adding color (e.g. red) to the product identifier to highlight that there is a difference between this product and other products

"Because if it's that important, people need to read that. They will read the name of the product and at the same time, when they see the label it says there is something very important, you can only have two cups a day or whatever it might be […] if you don't do it in your face, a lot of people might miss it."

"They [the caution] should be red and black. Red is attention grabber and you go right to that because you say what's this? It's in red. I think it should be red and somewhere here."

Understanding

Participants understood the nature of the risk associated with SF use.

"[…] So if they are warning you [in the caution box] that with this amount of vitamins, you should probably either drink this or have a multi [multivitamin], don't do both. And I thought that was pretty good personally."

They identified a need to place the supplemental ingredients information near the caution statement to highlight the link between the two pieces information.

"If you're looking at it [the caution box] for your decision making then when you're looking at the Nutrition facts table you are seeing it at the same glance. It's going to hit you. It's important that they be seen as one. But I think it's more important that it is linked to the Supplemented box as it is the caffeine that has the warning on the label. I think Supplement and Caution need to be seen in the same view"

Appraisal

Participants stated they would avoid consuming supplemented foods. Many started questioning the purpose of the supplementation and its implications on one's health. Many were concerned for their children and the risk associated with the presence of such a food at home without direct supervision. This led consumers to reject SFs from use in their own diet, and state that they should not even exist in the food market.

"I mean when you're quick shopping, "oh this looks kind of cool" and "oh it's supplemented" and "oh it helps to build bones and teeth", I am going to grab that. And then I am going to take it at home, "oh there is caution/attention", I don't want this. I am not going to be able to manage how much my kids drink of this. I don't want to have to manage that. I want to be able to have the food that's in my house that they can help themselves with whenever they need to"

"Why would we even serve these things if they are not that good for us? What would we say that they are good for us when really they are not good for us? This is just confusing all around."

The table below (Table 4) highlights key quotes for every theme. The participant's health literacy level is specified in brackets at the end of every quote.

Table 4. Interviews – Task 3: Caution statement

Key Themes	Key sub-themes and Quotes	
	Labelling Designs	**Packaging Attributes**
Accessibility and Awareness	**Legibility** *"I chose the caution format with the large title that says caution. If it is, caution it's something that people should be aware of. A larger title just grabs the attention of the consumer."* *(adequate literacy)* *"It's bigger and where it says caution, it's bigger. It's more prominent. Because this I find important."* *(marginal literacy)* *"I find symbols communicate better than text. I am a mother, I have two young children and I work, it's really quick. We don't have time to read. But if there is something that is easy to identify […] I would like to see more guides that are based on symbols on the use of colors because it's better just everyone in general."* *(marginal literacy)* *"By seeing this caution, I mean, what is this? Why are they warning us and telling us to be careful? So, you will read it, it has to be obvious [chose the biggest title], and not hidden or something. If it's important, it has to be visible"* *(marginal literacy)* **Contrast** *"They* [the caution] *should be red and black. Red is attention grabber and you go right to that because you say what's this? It's in red. I think it should be red and somewhere here."* *(marginal literacy)*	**Proximity to other regulated information** *I will naturally go to it right after seeing the supplemental part* [after seeing the supplemented box, see the caution beside it]. *(adequate literacy)* *Because I want everything to be written at the same place. I don't have time, when I am grocery shopping, to look what's important to read. It all has to be put together.* *(adequate literacy)* *Because here we see what's in the bar* [in the supplemented box]*, then it tells us not recommended to these people because of the caffeine* [in the caution] *and then you could go see, easier, the amount of caffeine in it* [in the supplemented box]. *(adequate literacy)* *"This information needs to be all together, to be visible, beside the NFt, to the side, but with the LOI"* *(adequate literacy)* *[…] it has to be obvious, and not hidden or something. If it's important, it has to be visible […] on top of it [the NFt]. All a way to concentrate the information around it"* *(marginal literacy)* **On the Front-of-Pack** *"Place the label would be at the front, to give a good warning to people who don' t turn the product to see the labelling at the back"* *(adequate literacy)* *"I would want it right on the FOP so that it is boom the first thing they are going to see. Or maybe not the first thing but they're going to see "Caution"" (adequate literacy)* *"Because if it's that important, people need to read that. They will read the name of the product and at the same time, when they see the label it says there is something very important, you can only have two cups a*

		day or whatever it might be […[if you don't do it in your face, a lot of people might miss it." *(marginal literacy)*
Understanding the nature of the risk	**Legibility** *"For this container, this* [the bigger one, CAUTION/ATTENTION] *is a bit of an overkill so someone might look at it and go, ok, why is that so big? I better put that back on the shelf. This one* [smaller, Caution/Attention] *is warning them. It's adequate they ca see it* […] *It's warning them to only have a couple per day"* *(adequate literacy)* *"[…] So if they are warning you [in the caution box] that with this amount of vitamins, you should probably either drink this or have a multi [multivitamin], don't do both. And I thought that was pretty good personally."* *(adequate literacy)* *"[…] Because it's not 'caution' that's important, it's the accumulation of it. So, attention accumulation or something like that…and not attention. Because the person that thinks it's good will not even look at the attention because often the cautions are not useful for these people, because they got informed. So for me, it has to be attention to the accumulation or something like that that indicates that, a reminder, that if you take a vitamin in the morning, do not take this after […] In my opinion, the rest of the information, considering that there is already a lot of information written, we are not there to read. I think that attention to the accumulation is sufficient as information. The rest seems useless to me."* *(marginal literacy)*	**Proximity to other regulated information** *"Under the LOI, because here you see the LOI, beside it is the NFT, and then after it tells us to be cautious because, yes, there is that vitamin and that mineral, but in too much quantity, it could bring us problems* […] *because if you would put it the other side, you might not think of looking there, whereas here, you will see for example, how much calcium, how much vitamin and you see this* [caution] *beside it"* *(adequate literacy)* *"If you're looking at it [the caution box] for your decision making then when you're looking at the Nutrition facts table you are seeing it at the same glance. It's going to hit you. It's important that they be seen as one. But I think it's more important that it is linked to the Supplemented box as it is the caffeine that has the warning on the label. I think Supplement and Caution need to be seen in the same view"* *(marginal literacy)*
Appraisal of the risk	**Avoidance** *"If I saw a caution I wouldn't buy it. My first words would be "I don't eat stuff with CAUTION" on it". Plain and simple. If there is a caution on it I am not eating it. I mean I shouldn't be eating stuff with a caution on it…personally."* *(adequate literacy)* *"Why would we even serve these things if they are not that good for us? What would we say that they are good for us when really they are not good for us? This is just confusing all around."* *(marginal literacy)* *"I mean when you're quick shopping, "oh this looks kind of cool" and "oh it's supplemented" and "oh it helps to build bones and teeth", I am going to grab that. And then I am going to take it at home, "oh there is caution/attention", I don't want this. I am not going to be able to manage how much my kids drink of this. I don't want to have to manage that. I want to be able to have the food that's in my house that they can help themselves with whenever they need to"* *(marginal literacy)*	

Discussion Groups - Task 1: Identify a supplemented food

Access/Awareness

Participants of varying health literacy levels were able to use both current and tested labelling approaches to identify SFs. Participants needed the wording "supplemented/supplémenté" on the FOP as stand-alone text (current labelling) or within a product identifier (tested labelling) to identify a supplemented food.

"[…] The granola crunch right on the very front in larger writing it says supplemented with niacin, riboflavin and Vit B12 […] certainly this with it written right on the front, it gets your attention" **[Current labelling]**

"Quite easy [to find the product identifier] *cos it has the word supplemented and it also has the symbol "S" on it"* **[Tested labelling]**

Consistency in placement was an important consideration as over time, the information would become familiar and easy to find.

"I am so confused now with all this. These two bottles both have the sign on them that it's supplemented. I would prefer that it was one spot that they put it, right, so that you don't have to kind of search for it"

Understanding

Participants needed the wording "supplemented/supplémenté" on the front of the package either as a stand-alone (in current labelling) or within a product identifier (in tested labelling) to understand the meaning of the letter "S". Some felt that the wording alone was less distracting and less confusing considering the presence of many symbols on foods nowadays.

"I like the logo for S for supplemented on the FOP. Whatever is on the back this sets it up that it is supplemented" **[Current labelling]**

"This one was flat out easiest [on the granola crunch]*, it says full on supplemented. The symbol S, there is so many symbols, it could be a trademark or anything, I would not have just assumed, I would kind of have to pause and read. Like, this one* [on the granola crunch]*, says supplemented with, this one is just basic."* **[Tested labelling]**

The table below (Table 5) highlights key quotes for every theme. The participant's health literacy level is specified in brackets at the end of every quote.

Discussion Groups

Table 5. Discussion Groups - Task 1: Identify a supplemented food

Key Themes	Key sub-themes and Quotes	
Accessibility and Awareness	**Tested labelling**	**Legibility** *"for me it was the S [that captured the attention], it wasn't just the written part [on the granola crunch, just the words "supplemented with"]"* (marginal literacy) *"Quite easy [to find the product identifier] cos it has the word supplemented and it also has the symbol "S" on it."* (marginal literacy) **Consistency** *"I am so confused now with all this. These two bottles both have the sign on them that it's supplemented. I would prefer that it was one spot that they put it, right, so that you don't have to kind of search for it"* (adequate literacy)
	Current labelling	**Legibility** *"The word supplemented got my attention"* (marginal literacy) *"on the red cereal [granola crunch], I noticed that they had the supplemental label right on the front […] because it's got supplemented on the bottom of it, on the front of the box, you'd see that"* (adequate and marginal literacy) *"[…] The granola crunch right on the very front in larger writing it says supplemented with niacin, riboflavin and Vit B12 […] certainly this with it written right on the front, it gets your attention"* (marginal literacy) *"I didn't even look on the side because it says supplemented with [on front of the granola crunch], so right away that was supplemented. This one took a second to find the logo [synergy flakes]"* (adequate literacy)
Understanding	**Tested labelling**	**Recognition** *"well this [the symbol] gives you an indication to go look at what actually has been supplemented"* (adequate literacy) *"The big S on the front tells me it's supplemented"* (translated from French) (marginal literacy) *"I like the logo for S for supplemented on the FOP. Whatever is on the back this sets it up that it is supplemented so if there is a public education campaign on recognizing that logo that would be a good start"* (marginal literacy)
	Current labelling	**Legibility** *"This one was flat out easiest [on the granola crunch], it says full on supplemented. The symbol S, there is so many symbols, it could be a trademark or anything, I would not have just assumed, I would kind of have to pause and read. Like, this one [on the granola crunch], says supplemented with, this one is just basic."* (adequate literacy)

Discussion Groups: Task 2 - Identify the type and amount of Supplemental Ingredients

Access/Awareness

On mock-ups labelled with the current labelling strategy, participants used information such as the NFt or the LOI or the FOP claims to try and determine the type of supplemental ingredients. However, they were uncertain of the type and amount of supplemental ingredients.

"[…] I couldn't figure out what this, we looked all around and we couldn't guess […]"

On mock-ups labelled with the tested labelling, participants of varying health literacy levels noticed the tabular format of the supplemental ingredients, noting that the presence of a bold separate heading followed by a listing of the supplemental ingredients was easy to read and follow.

"The Crave+ recover was excellent cos it had the nutrition [NFT] *and the supplements [SF box] and they were listed, not drawn out – listed in a form […] It was recognizable cos there was a lot of white around it, not a lot of other stuff."*

Understanding

With the mock-ups labelled using current labelling strategies, participants were unsure of the nature of the supplemental ingredients. The absence of a distinct section listing these ingredients created confusion among participants:

"It doesn't directly tell you, like there is vitamins in it, but it doesn't directly tell you on a separate label that this is supplemented with this or that there is caution to it or whatever. Like it doesn't say that anywhere on it"

With the mock-ups labelled using tested labelling strategies, participants were confused by the similar presentation of the ingredients in the supplemental ingredients' box and the NFt. Participants had difficulty understanding the different meaning behind each piece of labelling information. Sources of confusion were, for example, the presence of percent daily values in one

and not the other, as well as the presence of the same nutrients in both labelling elements. In addition, many of the supplemental ingredients were unfamiliar in nature, consequently raising questions as to what they are. Some started questioning the benefit of these supplemental ingredients and how much they should be consuming to get a benefit. Participants also assumed that the front-of-pack claims were about the supplemental ingredients, on both mock-ups with current and tested labelling strategies.

"it [nutrition information] *kind of repeats itself, right because you have the vitamins listed here* [in the SBox] *and then here* [in the NFt]*, like for the B* [vitamins] *and all that"*

"Some of it [ingredients in the supplemental box]*, we don't really understand what these words are, like a lot of people would not know what these words are, if they could be in words that people would understand, like sugar or something, then it might be easy"*

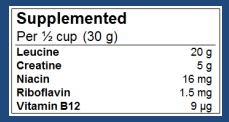
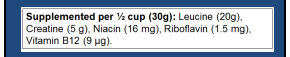
Appraisal

Appraisal of the tested labelling tools for the supplemental ingredients was triggered by its similar look and feel to the NFt. The black writing within a white framed box in the tested labelling gave it a feel of credibility and assurance that it is government-regulated.

"because when I look at this, maybe an assumption, when I see these boxes [on the side panel], these black and white boxes, these are official boxes that I think someone has told them, like Health Canada, they have to be very very specific, they have to include this information in there"

The table below (Table 6) highlights key quotes for every theme. The participant's health literacy level is specified in brackets at the end of every quote.

Table 6. Discussion Groups - Task 2: Identify the type and amount of Supplemental Ingredients

Key Themes	Key sub-themes and Quotes	
Accessibility and Awareness	**Tested labelling** Tabular  **Supplemented** Per ½ cup (30 g) **Leucine** 20 g **Creatine** 5 g **Niacin** 16 mg **Riboflavin** 1.5 mg **Vitamin B12** 9 µg Linear  **Supplemented per ½ cup (30g):** Leucine (20g), Creatine (5 g), Niacin (16 mg), Riboflavin (1.5 mg), Vitamin B12 (9 µg).	**Legibility** **Separate distinct title (heading)** *"because the two words that are important, the "supplement" and the "caution" are in bold and on one line, and it's easier for us, our eyes will read in one line"* *(adequate literacy)* *"The Crave+ recover was excellent cos it had the nutrition [NFT] and the supplements [SF box] and they were listed, not drawn out – listed in a form […] It was recognizable cos there was a lot of white around it, not a lot of other stuff."* *(marginal literacy)*
	Current labelling	**Confusion** *"[…] I couldn't figure out what this, we looked all around and we couldn't guess. So right on the front, supplement and then, because you got that there [the claim], assuming the leucine is the supplement, that would be helpful, because we were sort of guessing"* *(adequate literacy)* *"This one, I actually had to read the whole ingredient listing [on the tropical twist]. First I went to the NFt and it's just telling you the calories and the fat and the protein and all that, and then the vitamins, but it's not telling you on there if the vitamins are part of the juice that's in it or if it's supplemented. So I had to go to the actual ingredient listing, which is quite small, and that's where it's got the ingredient encapsulated fish oil and fish gelatin and so that's added, so that was the hardest one out of them all"* *(adequate literacy)* *"This I found just on the front (nutrition claims on Tropical Twist) – On the FOP it just says a source of Vit E, C and omega-3. That's about it. You couldn't find anything more about the supplemented ingredients"* *(marginal literacy)*
Understanding	**Tested labelling**	**Recognition** *"If I wanted to know how much it's supplemented with, I would look at the label [the supplemented box] to see how much was in there."* *(marginal literacy)* *"Now that I know, since we've been talking, now that I know, I look to the side [for the supplemented box]. That's the reason why there needs to be education. And some of these terms, like niacin, I don't see niacin and isoleucine and valine, I have no clue what purpose it has for me. So will it make a difference for me? I don't know, probably not, unless I educate myself on how that's going to benefit me"* *(adequate literacy)* *"Some of it [ingredients in the supplemental box], we don't really understand what these words are, like a lot of people*

		would not know what these words are, if they could be in words that people would understand, like sugar or something, then it might be easy" (adequate and marginal literacy) **Confusion** *"it [nutrition information] kind of repeats itself, right because you have the vitamins listed here [in the SBox] and then here [in the NFt], like for the B [vitamins] and all that" (adequate literacy)* *"how much creatine should I be getting, like what's a good amount and what's, depending on how much you're doing* [exercise], *how much extra you need* [of creatine]*" (adequate literacy)*
	Current labelling	**Confusion** *"Yah you don't know like, it seems to be a confusion on what is a supplement and what is not, like fish oil, is that a supplement? I don't know, is fish gelatin a supplement?" (adequate and marginal literacy)* *"on that one [the vegacrave], if you turn up this [the flap], it has the ingredients and if you go to the end, you sort of read it through and see what's sort of not part of it, so then it starts, after it lists all the ingredients, after organic flax seed, then it lists what I think are the supplements, creatine, niacin, riboflavin, vitamin B12 and ascorbic acid. But you have to sort of go through all the ones and then realize, oh they added the supplements, there is no other way to see the supplement " (adequate literacy)* *"This one isn't specifically labeled that it is supplemented [tropical twist]. However, on the front it does say that it's a source of vitamin C, vitamin E and omega-3. And when you look at the back, under the NFt, it actually says that it has vitamin E 4%, vitamin C 10% of the daily value and vitamin E 13%. And then it says 5% or less is little and 15% or more is a lot. So it actually is telling you if you are getting a little bit of a source or a lot" (adequate literacy)* *"It doesn't directly tell you, like there is vitamins in it, but it doesn't directly tell you on a separate label that this is supplemented with this or that there is caution to it or whatever. Like it doesn't say that anywhere on it" (adequate literacy)*
Appraisal	**Tested labelling**	**Credibility** *"because when I look at this, maybe an assumption, when I see these boxes [on the side panel], these black and white boxes, these are official boxes that I think someone has told them, like Health Canada, they have to be very very specific, they have to include this information in there" (adequate literacy)*

Discussion Groups: Task 3 - Identify any caution for use

Access/Awareness

Participants had greater difficulty finding the caution for use with the current labelling strategy compared with the tested labelling strategy. Current labelling attributes for the caution were not easy to locate because no heading or box was used to frame the information.

"The Vegacrave, it actually doesn't say caution, it just says do not eat more than one bar. So you may or may not read that, if there's not caution [no heading]. *I saw it [do not eat more than one bar] because I was looking for it* […] *there is so much writing on something like this that you might miss the do not eat more than 1 bar per day, because it's not telling you caution"*

One factor increasing the noticeability of the tested version was information grouped in a framed box with a separate, distinct heading. In addition, placement of this information near other commonly used regulated nutrition information facilitated access and awareness. Participants, particularly those at risk of marginal health literacy, mentioned a need for color or a symbol on the front-of-pack to highlight the presence of a caution.

"So all in one spot, it's a lot faster. I think if you have to struggle to find the information, you're either going to ignore the cautions and the warnings or just put it back"

"some kind of big red flag on the front saying, read these cautions before giving to anybody"

"If It had a big R in red on the circle so that you know it's restricted that would be, cos some of them are restricted…to children"

Understanding

With mock-ups labelled using the tested labelling strategy, participants linked the caution to the supplemental ingredients when these two labelling elements were placed next to each other (beside or above/below). The caution also triggered questioning of the benefit of supplemented foods. There was uncertainty as to the purpose of these supplemental ingredients.

"Well I think for me, there is an assumption that supplemented is good, more is, so it's supplemented right, that's a good thing, it's vitamins, it's this it's that. And that's not necessarily the case for everybody so there has to be some sort of education that supplement does not equal good for you.

Because it may be something that's not good for children, it may be something that you're still sensitive too, so for me, it's almost like you have to educate people that sure supplement is good and it serves a specific purpose but for me, I would want to be able to navigate and understand well why are we supplementing foods? Like what, now, why is that good?"

Appraisal

For both labelling strategies, participants of varying health literacy levels declared complete avoidance of these foods because of the cautionary labelling on them.

"I ain't going to eat it, I wouldn't buy it"

"I ask myself what are they putting all these vitamins in? Is the food not good enough to begin with? It's not natural food anymore. I think the quality of our food has gone down"

Figure 5. Final Labelling Tools

The table below (Table 7) highlights key quotes for every theme. The participant's health literacy level is specified in brackets at the end of every quote.

Table 7. Discussion Groups - Task 3: Identify any caution for use

Key Themes	Key sub-themes and Quotes	
Accessibility and Awareness	**Tested labelling**	**Legibility** **Separate distinct title (heading)** *"And I prefer this one for whatever reason [labelling on Crave Bar with caffeine]. So they are both on the back, but they have supplemented and caution in nice big bold letters and it says what it is"* *(adequate literacy)* **Contrast** **Color** *"some kind of big red flag on the front saying, read these cautions before giving to anybody"* *(adequate literacy)* *"If It had a big R in red on the circle so that you know it's restricted that would be, cos some of them are restricted…to children"* *(marginal literacy)* *"The red circle (for the caution) with the red bar through it – so right away you would know – and put it right next to the SF logo so people would know right away"* *(marginal literacy)* **Proximity to other regulated information** *"So all in one spot, it's a lot faster. I think if you have to struggle to find the information, you're either going to ignore the cautions and the warnings or just put it back"* *(adequate literacy)* *"We turned to the side to see it – you'd see it right away. Not on the front. Most people you know look at the side don't you? to see what's on your cereals. I would think most people would"* *(marginal literacy)* *"I always go to the ingredients first so I think the caution should be right there"* *(marginal literacy)*
	Current labelling	**Legibility** *"The Vegacrave, it actually doesn't say caution, it just says do not eat more than one bar. So you may or may not read that, if there's not caution* [no heading]. *I saw it [do not eat more than one bar] because I was looking for it* […] *there is so much writing on something like this that you might miss the do not eat more than 1 bar per day, because it's not telling you caution"* *(adequate literacy)*
Understanding	**Tested labelling**	**Proximity to other regulated information** *"I can see the supplements [in the SBOx] and then oh what do I need to be aware of with these supplements, as opposed to if you separate it, ok these are the supplements, what do I need to worry about? What a second, how many milligrams of whatever is in there?"* *(adequate literacy)*

		"This becomes a recognizable [the symbol], as we are talking about this, the dangers why these are not for children, why these are not for, you can only eat 1 or 2 in a day, is because of the supplements. So I think [….] if this logo, for supplemented was properly marketed […] would market this as saying caution, these are supplemented, these are like taking vitamins so you can check the label for how much you can take and not intended for children" (adequate literacy)
	Tested & Current labelling	**Confusion** *"Well I think for me, there is an assumption that supplemented is good, more is, so it's supplemented right, that's a good thing, it's vitamins, it's this it's that. And that's not necessarily the case for everybody so there has to be some sort of education that supplement does not equal good for you. Because it may be something that's not good for children, it may be something that you're still sensitive too, so for me, it's almost like you have to educate people that sure supplement is good and it serves a specific purpose but for me, I would want to be able to navigate and understand well why are we supplementing foods? Like what, now, why is that good?" (adequate literacy)*
Appraisal	**Tested & Current labelling**	**Avoidance** **Avoidance of the caution information** *"I would want to see yah creatine, 10 mg and frankly, if I was looking for that, I probably don't care about the caution. I'll be like ok I want that creatine, I don't care if I can have 2 bars or 3 bars, someone's probably said hey you should get this and follow their advice so the caution is probably something, like I wouldn't worry as much about that. Even the caffeine, I don't worry to take in a lot of caffeine to be a problem right so, cause I know I wouldn't worry about a caution" (adequate literacy)* **Avoidance of the food** *"I ain't going to eat it, I wouldn't buy it" (marginal literacy)* *"I think most people would not be eating that after all those warnings" (adequate and marginal literacy)* *"well it's like you can only have so much and then you are getting too much, so maybe I shouldn't even be drinking this" (adequate and marginal literacy)* *"I ask myself what are they putting all these vitamins in? Is the food not good enough to begin with? It's not natural food anymore. I think the quality of our food has gone down" (marginal literacy)*

Chapter V
Discussion

Interviews and discussion groups with consumers in the National Capital Region and the surroundings revealed various salient labelling attributes that would help consumers identify SFs, the type and amount of supplemental ingredients, and any directions or caution for use of these products. These include a front-of-pack, text-based, SF product identifier to ensure awareness and recognition of supplemented foods. The symmetry of the circular symbol, the clarity of the letter "S" and the recognizable wording "Supplemented/Supplementé" within the symbol helped consumers to seek and find SFs. Essentially, it is the wording "Supplemented/Supplementé" on the front-of-pack that is key for consumer recognition of a SF.

Misunderstanding arises with the presence of claims on the FOP. Often, the claims are about the supplemental ingredients, but that is not always the case. With participants placing the SF identifier near the claims to create a mental link (i.e. this food is supplemented with the ingredients highlighted in the claim), that could lead to misunderstanding if the claim is not about a supplemental ingredient. Regulations surrounding use and proximity of claims to SF labelling may need to be outlined when developing a supplemented food framework.

Integration of a prominent "Supplemental Ingredients" box in proximity to the Nutrition Facts table facilitates awareness of the type and amount of the supplemental ingredients. The tabular format was easily recognizable due to its similar look and feel to other familiar nutritional information (i.e. the nutrition facts table), and the presence of a distinct "Supplemented" heading. It's important to note that packaging size (i.e. available display surface) may influence the accessibility of labelling attributes. While a horizontal listing format was easiest to read, the linear format was more accessible on smaller packaging, such as bars,

due to its significantly smaller size and landscape orientation.

Understanding of the nature and type of supplemental ingredients was difficult for many participants. In particular, those participants at risk of marginal health literacy expressed difficulty understanding the meaning behind the supplemental ingredients box compared with the NFt. To them, the supplemental ingredients box was simply repeating the information found in the Nutrition Facts Table. This reasoning is justifiable when a product is supplemented with nutrients such as amino acids, fatty acids, vitamins and/or minerals, as they would then be listed in both the supplemental ingredients box and the Nutrition Facts Table. Yet other supplemental ingredients such as herbals (e.g. ginseng) and bioactives (e.g. caffeine) would appear only in the Supplemental ingredients listing. There is much complexity in the principles behind both labelling attributes which would need to be addressed with extensive awareness and education campaigns with health intermediaries as well as consumers.

Another understanding issue arises with those of adequate health literacy, who requested the addition of a percent daily value in the supplemental ingredients box. Many of the supplemental ingredients do not have an established daily value because they are not daily required nutrients. This means that a percent daily value cannot be identified. Such an explanation needs to be communicated in a consumer education campaign.

An extra layer of complexity is added with foods that may contain added ingredients, such as vitamins and minerals, for fortification purposes (e.g. Vitamin D in milk) or enrichment purposes (e.g. B vitamins in rice). Distinguishing fortification from enrichment from supplemented will need to be addressed with health intermediaries and consumer education campaigns.

The addition of a prominent “Caution” section, with its placement in a distinct clutter-

free area close to other regulated label information, improved the credibility of the tested approach (i.e. it was perceived as a government-regulated piece of information, and thus, trustworthy). Placement of the caution statement below or adjacent to the supplemental ingredients information facilitated the linking of the caution to the supplemental ingredients. Consumers were particularly wary of supplemented foods due to the presence of cautionary statements on many of them. To mitigate that concern, consumers discussed placement of the cautionary labelling on the front-of-pack. This could simply involve having the word "caution" on the FOP or adding color (e.g. red) to the product identifier to highlight that there is a difference between this product and other products. This approach was particularly salient to participants of marginal health literacy because the message was conveyed easily and simply and didn't require extensive mental processing in order to understand its meaning. This aligns with other research that shows that while many consumers rely on heuristics, to do this they need simple and direct messages on the FOP (Antúnez et al., 2015; Becker et al., 2016; Bialkova & van Trijp, 2010; van Herpen & Trijp, 2011; Pieters & Warlop, 1999). From a regulatory perspective, although SFs are safe to consume, there is a need for cautionary labelling that highlights specific guidelines for use of the SF product. This information needs to be easily found and understood. Awareness and education campaigns would help increase awareness of the presence of caution and understanding of the specific guidelines for appropriate use of specific SFs.

When comparing current and tested labelling strategies, both text-based (current labelling) and symbol-based (tested labelling) FOP SF identifiers were accessible and helpful to consumers of varying health literacy levels to identify a supplemented food. The wording "supplemented/supplémenté" was the key element needed on the FOP, by itself or incorporated

into a product identifier.

The current labelling strategy is insufficient for identifying the nature of the supplemental ingredients and any caution for use. These pieces of information are not clearly highlighted on the label; the type and amount of the supplemental ingredients are not always listed; and the caution statement is not presented in a consistent, clear manner. The lack of labelled supplemental ingredient information, in particular about the amount of each supplemental ingredient, pushed participants to search out and try to use other pieces of information, such as the Nutrition Facts Table and the List of Ingredients, to generate information about the nature and type of supplemental ingredients. These regulated pieces of labelling information are familiar to consumers and they often seek out these pieces of information to make food-related decisions (Canadian Council of Food and Nutrition, 2009; Cowburn & Stockley, 2005). In the case of supplemented foods, these pieces of label information do not provide the information consumers need. Paramount for SF is consumer awareness and education campaigns on SF labelling attributes to ensure awareness and use of the appropriate pieces of information to make an informed SF choice.

For a consumer to make an informed choice with respect to a SF, he must be able to (1) access the correct SF information, (2) understand what it means, and (3) apply it in the context of his own dietary goals/needs. The inclusion of consumers of varying levels of health literacy helped identify salient labelling attributes that help consumers, particularly those disadvantaged by limited/marginal health literacy, to make informed food choices when it comes to supplemented foods. This health literacy lens is novel for Canadian food labelling research and should be a consistent component of all future labelling research so as to reduce health inequities. Health literacy spans to include the moderating effect of personal determinants (e.g.

age, gender, and race), situational determinants (e.g. social support, family and peer influence) as well as societal and environmental ones, including food industry advertising, food marketing and on-package labelling of nutrition information (Sorensen et al, 2012). By using this all-encompassing lens, we can develop better labelling tools to help consumers make informed food-based decisions.

There are limitations to this research. First and foremost is the novelty and complexity of supplemented foods. The definition is complex and proved to be extremely difficult to translate into plain language in order to be communicated to participants. Unfortunately, we did not assess consumer understanding of our explanation of SFs. In addition, the mock-packages used (i.e. cereals, beverages and bars) might not be products normally bought or consumed by the participants, so that may have created a barrier in their interaction with the labelling tools.

Findings from this research are helping to inform a nation-wide mock package trial that will objectively test the key set of labelling tools identified in our study among a larger sample of Canadians. This mock-package trial will help clarify whether a symbol-based or text-based approach on the FOP might be sufficient to identify supplemented foods. It will also help to compare, on a larger scale, the effectiveness of current versus tested labelling attributes for the supplemental ingredients and the caution statement. This will help generate evidence-based information that will be used to inform government in developing labelling strategies and specifications for SFs, including design specifications, label placement and specific templates in accordance with the principles of plain language labelling. Furthermore, it will support identified education/outreach activities that will be needed to bridge the gaps in consumer understanding and informed use of SFs.

Chapter VI
Conclusion

To make an informed supplemented food choice, a consumer must be aware of what information they need to seek and find in order to identify a SF, to understand the nature of the supplemental ingredients, and to evaluate the SF in the context of their own dietary goals/needs. This study helped identify a key set of labelling tools for SFs to be included on the FOP and on the BOP to help consumers access, understand and appraise SFs properly. First, a circular product identifier on the FOP with the letter "S" and the wording "supplemented/supplémenté" helped consumers distinguish SFs from conventional foods. Second, a supplemental ingredients box with a distinct heading "Supplemented/Supplémenté" adjacent to a caution statement with a distinct heading "Caution/Attention" helped consumers identify the nature of the supplemental ingredients as well as the caution to be taken with product use. There were gaps in understanding the difference between the information found in the NFt and that found in the supplemental ingredients box. There were also gaps in understanding of the rationale for these foods, in particular those that have unfamiliar supplemental ingredients as well as those that have cautionary labelling. This led consumers to reject SFs from use in their own diet and question the very existence of these products on the market. Extensive awareness and education campaigns with health intermediaries as well as consumers will be needed to ensure proper understanding of the nature of these foods. In addition, more research is required to ensure the effectiveness of the tested labelling tools to be used on SFs.

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Appendices

Appendix A: Interview labelling tools

Product Identifier – Design Options

Supplemented Ingredients - Design Options

Supplemented	
Per ½ cup (30 g)	
Leucine	20 g
Creatine	5 g
Niacin	16 mg
Riboflavin	1.5 mg
Vitamin B12	9 µg

Tabular

Supplemented per ½ cup (30g): Leucine (20g), Creatine (5 g), Niacin (16 mg), Riboflavin (1.5 mg), Vitamin B12 (9 µg).

Linear

Caution Statement - Design Options

Uppercase

Caution

Do not exceed 1 serving per day. Eat ½ cup (30g) before or after exercise for maximum benefit.

Separate Title

CAUTION: Do not exceed 1 serving per day. Eat ½ cup (30g) before or after exercise for maximum benefit.

Caution: Do not exceed 1 serving per day. Eat ½ cup (30g) before or after exercise for maximum benefit.

Lowercase

Appendix B: Semi-structured interview guide

Introduction (1minute)

Moderator *(italics for speaking* notes):
Introduce self and role in this research for Health Canada.
Many people find it hard to understand food labels. We want to learn what parts of food labels are most confusing. We will ask you to look at a *food label from some ice cream* **(give participant ice cream container with NFt of NVS).**

We will then ask you six questions about the food label.

This information is on the back of a 500-ml container of ice cream.

	ANSWER CORRECT?	
	Yes	No
1. If you eat the entire container, how many calories will you eat? *Answer: 1,000 is the only correct answer*		
2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream can you have? *Answer: Any of the following is correct: 250 ml or 1 cup (or any amount up to 250 ml or 1 cup), half the container. Note: If the patient answers "two servings", ask "How much ice cream would that be if you were to measure it into* a *bowl?"*		
3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be eating each day? *Answer: 33 is the only correct answer*		
4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving? *Answer: 10% is the only correct answer*		
Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves and bee stings.		
5. Is it safe for you to eat this ice cream? *Answer: No*		
6. (Ask only if the patient responds "No" to question 5) Why not? 7. *Answer: Because it has peanut oil and contains peanut.*		

Interpretation

Score of 0-3: M (marginal health literacy)
Score of 4-6: A (adequate health literacy)

Number of correct answers:

Nutrition Facts

Serving Size 1/2 cup (125 mL)
Servings Per Container 4

Amount Per Serving	% Daily Value*
Calories 250	
Fat 13 g	**20** %
Saturated 9.0 g + Trans 0 g	**45** %
Cholesterol 30 mg	
Sodium 55 mg	**2** %
Carbohydrate 30 g	**10** %
Fibre 0 g	**0** %
Sugars 23 g	
Protein 4 g	

Vitamin A	10 %	Vitamin C	0 %
Calcium	15 %	Iron	4 %

* Percentage Daily Values are based on a 2,000 Calorie diet. Your daily values may be higher or lower depending on your Calorie needs.

INGREDIENTS: Cream, skim milk, liquid sugar, water, egg yolks, brown sugar, milkfat, peanut oil, sugar, butter, salt, carrageenan, vanilla extract

Moderator to explain what a SF is:

- There are new foods and drinks on the market with ingredients such as caffeine and herbals (for example: ginseng) and high levels of added vitamins and minerals compared to regular foods
- Many of these supplemented foods will need directions for use and caution statements on the label to ensure that they are being used safely by consumers.
- Health Canada has decided to call these foods: "Supplemented foods".
- We want your help to know how to best to label these supplemented foods so that you can easily identify them and also be able to use them safely if you choose to do so.

Do you have any questions before we start?

Task 1 (10 minutes)

Moderator to explain the task:

- This cereal is a supplemented food. It is supplemented with Leucine, an amino acid, and high amounts of 3 B vitamins: niacin, riboflavin and vitamin B12. This cereal can help maintain muscle mass [**SENIORS**], [**PARENTS**], help with recovery post workout [**PHYSICALLY ACTIVE**]. To get these benefits a person has to eat ½ cup of cereal after exercising.

A. Health Canada has developed 6 different approaches so that so that you can quickly and easily identify that it is a SF.
    - I would like you to rank these based on your most preferred to your least preferred approach. Then we will discuss your choices.
      Give them a few minutes.
    - Let's talk about your choices.
      Probe on choices:
        - Which is your preferred choice? Why did you choose this piece?
        - How important (or not) is it to include the wording "Supplemented" with the symbol?
        - What is your least preferred approach to identify an SF?
        - Why?
    - Now I would like you to label the cereal so that you can quickly and easily identify that this cereal is a supplemented food. Here are different sizes of your preferred choice. Please choose a size and place it on the package where you think it is quickest and easiest to see.
      Give them a few minutes
    - Let's talk about where you placed your label information- probe on chosen size and placement on package
        - Why did you choose this size?
        - Where on the package did you place this piece of information?
        - Why there and not somewhere else on the package?

B. As I mentioned before, this cereal is supplemented with Leucine and high amounts of 3 8 vitamins: niacin, riboflavin and vitamin B12.

- Health Canada has developed 2 different labelling approaches to do so: a supplemented box or a supplemental list of ingredients **(show participant piece of paper with the two approaches)** to help you identify the type and amount of supplemental ingredient (s).
  Probe on CHOICE:
  - Which one do you prefer?
  - Why did you prefer this one compared to the other one?
- Now that you we've discussed your preferences, here are different sizes of your preferred approach. I would like you to label the cereal so that you can quickly and easily identify the type and amount of all the supplemental ingredients.
  Probe on SIZE and PLACEMENT:
  - Why did you choose this piece (size) of labelling information?
  - Where did you place this piece of information?
  - Why there and not somewhere else on the package?

Task 2 (10 minutes)

- For task #2, we will use a supplemented drink. This drink is supplemented with high amounts of 1 mineral and 1 vitamin:

  SENIORS: Calcium and Vitamin D. A healthy diet with adequate calcium and vitamin D, and regular exercise, help to achieve strong bones and may reduce risk of osteoporosis.This beverage is very high in calcium and vitamin D.

  PARENTS: Calcium and Vitamin D. Calcium and Vitamin D help build and maintain strong bones and teeth.

  PHYSICALLY ACTIVE: Magnesium and Vitamin. Magnesium and Vitamin D contributes to normal muscle function and maintenance of strong bones

A. Using your preferred choice from Task 1, choose your preferred size of SF symbol and place it on this drink container so that you can quickly and easily identify that it is supplemented food.
   Give them a few minutes.
   - Let's talk about where you placed your label information.
     Probe on chosen size and placement on package for SF symbol:
     - Why did you choose this size?
     - Where on the package did you place this piece of information?
     - Why there and not somewhere else on the package?

B. As I mentioned before, this drink is supplemented-with high amounts of calcium/magnesium and Vitamin D. Here are the 2 different labelling approaches: a supplemented box or a supplemented list of ingredients **(point it out on the sheet)** with the supplemental ingredients for the drink. Choose the format and size you prefer and place this SI information on the drink container so that you can quickly and easily identify the type and amount of the supplemental ingredient (s).
   Give them a few minutes.

Probe on choice and placement:

- Why did you choose this piece of labelling information?
- **If it is different from the cereal choice, ask:** why did you choose a different approach?
- Where and why did you place this piece of information?
- Why there and not somewhere else on the package?

C. The label of this drink also has to tell people how to use it and who should NOT use it. Do not drink more than 2 cups per day. Do not drink this product with other supplemented foods. If you take a daily vitamin and/or mineral supplement, you may be getting too much vitamins and/or minerals by drinking this product.
Choose the label information you need so that you can quickly and easily identify this caution and place it on the package.
Probe on choice and placement:

- Why did you choose this piece of labelling information?
- Where and why did you place this piece of information?
- Why there and not somewhere else on the package?

Task 3 (10 minutes)

Repeat as for task #1 and 2. Furthermore, the label does not have enough space to include the full set of labelling options as the larger packages.

A. I am now going to give you a supplemented bar. This organic bar is supplemented with caffeine and 4 B vitamins: Riboflavin, Niacin, Vitamin B6 and Vitamin 8\B12.

SENIORS AND PARENTS: the caffeine content helps maintain physical and mental alertness

PHYSICALLY ACTIVE: The caffeine content helps improve endurance and mental performance

- Choose the size of your preferred SF symbol and place it on this bar so that you can quickly and easily identify that it is supplemented.
Probe on choice (size) and placement:
  - Why did you choose this size?
  - Where on the package did you place this piece of information?
  - Why there and not somewhere else on the package?

B. As I mentioned before, this organic bar is supplemented with caffeine and 4 8 vitamins: Riboflavin, Niacin, Vitamin 86 and Vitamin 812. Here are the 2 different labelling approaches that Health Canada has developed for small packages such as this bar *(point it out on the sheet).* Choose the format and size you prefer and place this SI information on the bar so that you can quickly and easily identify the type and amount of the supplemental ingredient (s).
Probe on choice and placement:

- Why did you choose this piece of labelling information?
- **If it is different from the cereal choice, ask:** *why did you choose a different approach?*
- Where and why did you place this piece of information?
- Why there and not somewhere else on the package?

C. The label of this bar has to tell people how to use it and who should NOT use it.
It is not recommended for children, pregnant or breastfeeding women or individuals sensitive to caffeine. People should also not eat more than 2 bars per day. People should not eat this product with other supplemented foods.
Choose the label information you need so that you can quickly and easily identify this caution and place it on the package so that you can quickly and easily identify this caution
Probe on choice and placement:

- Why did you choose this piece of labelling information?
- Where and why did you place this piece of information?
- Why there and not somewhere else on the package?

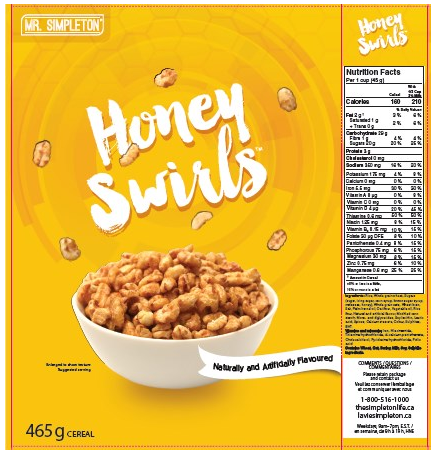
WRAP-UP

Moderator to place the 3 SFS packages in front of the participant and to take a picture of them for future analysis

Q: Before we finish the interview, do you have any questions on what we have been discussing?

Thank- you for volunteering to participate in this research.
Here is a $25 food voucher that you can use at your local grocery store.

Appendix C: Discussion group mock-packages



Conventional

Supplemented
Tested labelling

Supplemented
Tested labelling

Supplemented
Current labelling

Conventional

Supplemented
Tested labelling

Supplemented
Tested labelling

Supplemented
Current labelling

Conventional

Supplemented
Tested labelling

Supplemented
Current labelling

Supplemented
Tested labelling

Appendix D: Semi-structured discussion group guide

Introduction – 5 minutes

S'introduire et expliquer son rôle dans cette étude par Santé Canada

Avant de commencer la discussion, on va juste prendre quelques minutes pour passer à travers le formulaire de consentement ensemble. Vous avez deux copies devant vous; une copie sera pour moi, avec votre signature, et l'autre copie est à vous de conserver.

Pour commencer, et que pour qu'on se connaisse un peu mieux, parlons de nos choix alimentaires. Qui aimerait commencer par s'introduire et dire c'est quoi leur nourriture préférée.

- Explorer la nourriture que chaque individu mentionne (ex : *qu'est-ce que tu cherches ou regarde quand t'achète tes bananes?)*

Modérateur explique ce qu'est un aliment supplémenté :
De nouveaux aliments et breuvages avec des ingrédients ajoutés sont maintenant sur le marché. Ses ingrédients ajoutés peuvent êtres :

- *des herbes, par exemple ginseng ou guarana*
    - *Par exemple, on a le paquet de céréale ici avec du ginseng ajouté, qui pourrait aider avec la stimulation du système immunitaire ou pourrait avoir une influence sur la cognition*
    - *On a de la margarine ici avec des stérols végétaux, qui aident à réduire le cholestérol*
- *des ingrédients bioactifs, qui sont des ingrédients avec un effet sur le corps, sur le cerveau, sur votre performance… Un exemple serait de la caféine*
- *des quantités élevées de vitamines et minéraux comparés aux aliments réguliers*
    - *On a quelques exemples ici : eau vitaminé, une barre avec des vitamines*

Santé Canada a décidé d'appeler ses aliments des 'aliments supplémentés.'
La première chose avec laquelle nous avons besoin de votre aide aujourd'hui c'est de savoir à quel point c'est facile et rapide d'identifier si un produit est supplémenté ou non.

Tâche 1 – identifier un produit supplémenté (15 minutes)

On va vous mettre en groupe de 2 ou 3 personnes et on va donner à chaque groupe un ensemble de produits. Vous devez maintenant identifier si n'importe lequel des produits devant vous est supplémenté.

Questions :

- *Quel groupe aimerait commencer par partager ce qu'il a trouvé?*

Modérateur à explorer les pièces d'informations utilisées pour identifier un SF (utilisation)

- *Lequel des aliments/breuvages est un aliment supplémenté?*
  [Noter ceux qui n'identifient par le SF correctement – quelle information sur l'étiquette ont-ils utilisées/n'ont pas utilisées pour faire leur mauvaise évaluation?]
- *Comment as-tu décidé si ton aliment/breuvage est supplémenté ou non?*
- *À quel point c'était facile de trouver cette information?*

- *Si tu cherchais un aliment supplémenté particulier à l'épicerie, qu'est-ce qui t'aiderai à le trouver rapidement et facilement?*
    - *Autre que l'étiquette de l'aliment, qu'est-ce qui pourrait t'aider?*

Tâche 2 – type et quantité d'ingrédients avec lesquels un aliment est supplémentés (15 minutes)

*Maintenant, je vais donner à chacun d'entre vous **TROIS** aliments/breuvages supplémentés, chacun étiqueté de façon différente pour te dire quels sont les ingrédients avec lesquels l'aliment est supplémenté. Vous devez maintenant trouver quels ingrédients ont été ajoutés à tes produits. Go!*

Questions :

- *Qui aimerait commencer par partager les ingrédients ajoutés à ses produits?*
- *Comment sais-tu quels ingrédients ont été supplémentés à ton produit?*
    - Explorer information sur FOP vs BOP
    - Explorer les différences entre TMAL et SI (LOI ou Boîte)
- *À quel point c'était facile de trouver l'information sur les ingrédients avec lesquels le produit est supplémenté?*
    - *Est-ce que un type d'étiquette était plus facile à utiliser que les autres? Pourquoi?*
    - Explorer les différences entre la boîte de supplémentation et la liste de supplémentation : *à quel point c'est facile pour toi de lire et comprendre le type et la quantité d'ingrédients ajoutés quand c'est écrit dans une boîte vs une liste vs sur le devant du produit?*
    - *Qu'est-ce qui a rendu ce format plus facile que les autres?*
- *Qu'est-ce qui rendraient les ingrédients avec lesquels le produit est supplémenté encore plus facile à comprendre (TMAL)?*
    - *Comment?*
- *Quelle autre information sur les ingrédients avec lesquels l'aliment est suppléments voulez-vous sur les aliments supplémentés?*
    - *Pourquoi?*

Tâche 3 – directives d'usage des aliments supplémentés (15 minutes)

Donner à chaque participant un ensemble de produits différents (changer de catégorie).

Maintenant chacun va changer de produits; chacun va prendre des produits d'une autre catégorie. Pour cette dernière tâche, vous devez regarder et comparer vos produits pour trouver la mise en garde et/ou les directives d'usage sur vos aliments supplémentés.

Questions :

- *Qui aimerait commencer par nous dire la mise en garde ou les directives sur ses produits supplémentés?*
- *Comment savez-vous s'il y a des directives d'usage ou des mises en garde en lien avec l'utilisation de vos produits supplémentés?*
    - *Quelle information avez-vous utilisées pour identifier ceci?*
    - *Que signifie cette information pour vous? Qu'est-ce que ça vous dit?*

- *À quel point c'était facile de trouver cette information?*
    - *Qu'est-ce qui la rendrait plus facile? Comment ça serait plus facile dans ce cas?*
- *Est-ce que la mise en garde et/ou les directives d'usage devraient être placés proche de d'autres informations pour que ça soit plus facile à trouver et comprendre?*
- *Quelle autre information avez-vous besoin sur vos produits supplémentés? Pourquoi?*

Commentaires finaux et conclusion (3-4 minutes)

- *Si vous cherchez un aliment supplémenté spécifique, soit à l'épicerie ou sur internet, qu'avez-vous de besoin pour le trouver plus facilement?*
    - Explorer l'apparence de l'étiquette **vs** emplacement dans l'épicerie ou sur un site internet
    - *Pourquoi?*
- *Est-ce que quelqu'un aimerai ajouter quelque chose d'autre à la fin de notre discussion?*

Merci pour votre participation!
Voici votre carte-cadeau de $25 dans une épicerie locale.

Appendix E: Codebook

	Consumer Access	Consumer Understanding	Consumer Appraisal
	Seek, find and obtain the SF label information Low cognitive burden, especially when motivation, time are limited Is it legible / readable? • *Can they identify it quickly from amongst the other food label information?* • *Is it distinct from other package info, easy to find on label?*	**Relevance and sequence of SF label information** Awareness and understanding of the SI's • *Do they know to look for label information on SFs?* • *Do they perceive it as credible information?* • *What label information is relevant to their understanding of the nature of the SF (i.e. type and amount of SI)?*	**Interpret, filter, judge, and evaluate the label information** Are there any risks/benefits of this SF? • *What label info do they use to make their evaluations of the risks/benefits?* • *What is their decision making process (hierarchy of label info they use) to place that food within the context of their overall diet?*
Key components of a labelling strategy for these products to meet consumer needs are:	Label information consumers need to be able to identify and distinguish SFs from amongst other foods (small packages up to largest packages)	Label information consumers use to understand the nature of the SF (i.e. nature and quantity of the supplemental ingredients)	Label information consumers use to be able to appraise the risks/benefits of use of SFs and apply that information in the context of their dietary goals and needs

Appendix F: REB Approval Certificate

File Number: H10-16-11 **Date (mm/dd/yyyy):** 10/24/2016

Université d'Ottawa University of Ottawa
Bureau d'éthique et d'intégrité de la recherche Office of Research Ethics and Integrity

Ethics Approval Notice

Health Sciences and Science REB

Principal Investigator / Supervisor / Co-investigator(s) / Student(s)

First Name	Last Name	Affiliation	Role
France	Rioux	Health Sciences / Others	Supervisor
Mary	L'Abbé	Others / Others	Co-Principal Investigator
Elizabeth D.	Mansfield	Others / Others	Co-Principal Investigator
Elaine	de Grandpre	Others / Others	Co-investigator
Doris	Gillis	Others / Others	Co-investigator
Rana	Wahba	Health Sciences / Others	Student Researcher
Alyssa	Schermel	Others / Others	Research Assistant

File Number: H10-16-11

Type of Project: Master's Thesis

Title: PAUSE: Prevalence and consumers' Access, Understanding and use of Supplemented foods to inform labelling and Education in Canada (Studies A and B)

Approval Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
10/24/2016	10/23/2017	Approved

Special Conditions / Comments:
N/A

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File Number: H10-16-11 **Date (mm/dd/yyyy):** 10/24/2016

Université d'Ottawa University of Ottawa
Bureau d'éthique et d'intégrité de la recherche Office of Research Ethics and Integrity

This is to confirm that the University of Ottawa Research Ethics Board identified above, which operates in accordance with the Tri-Council Policy Statement (2010) and other applicable laws and regulations in Ontario, has examined and approved the ethics application for the above named research project. Ethics approval is valid for the period indicated above and subject to the conditions listed in the section entitled "Special Conditions / Comments".

During the course of the project, the protocol may not be modified without prior written approval from the REB except when necessary to remove participants from immediate endangerment or when the modification(s) pertain to only administrative or logistical components of the project (e.g., change of telephone number). Investigators must also promptly alert the REB of any changes which increase the risk to participant(s), any changes which considerably affect the conduct of the project, all unanticipated and harmful events that occur, and new information that may negatively affect the conduct of the project and safety of the participant(s). Modifications to the project, including consent and recruitment documentation, should be submitted to the Ethics Office for approval using the "Modification to research project" form available at: http://www.research.uottawa.ca/ethics/forms.html

Please submit an annual report to the Ethics Office four weeks before the above-referenced expiry date to request a renewal of this ethics approval. To close the file, a final report must be submitted. These documents can be found at: http://www.research.uottawa.ca/ethics/forms.html

If you have any questions, please do not hesitate to contact the Ethics Office at extension 5387 or by e-mail at: ethics@uOttawa.ca.

Signature:

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Appendix G: Interview Consent Form

Nutrition Labelling Research Project
Information and Consent Form for Individual Interviews

Project Researchers:

Elizabeth (Beth) Mansfield, PhD, RD, Health Canada, Ottawa, Ontario
Elaine de Grandpre, MHSc, RD, Health Canada, Ottawa, Ontario
Doris Gillis, PhD, RD, St Francis Xavier University, Antigonish, Nova Scotia
Mary L'Abbé, PhD and Alyssa Schermel, MSc, University of Toronto, Toronto, Ontario
Rana Wahba, BSc Dietetics, Master's Student, University of Ottawa, Ottawa, Ontario

Organizations:

Bureau of Nutritional Sciences, Food Directorate, Health Canada, Ottawa, Ontario
Department of Nutrition, St Francis Xavier University, Antigonish, Nova Scotia
Department of Nutritional Sciences, University of Toronto, Toronto, Ontario
Department of Health Sciences, University of Ottawa, Ottawa, Ontario

Participant Name: _____

Assigned Group ID: _____

Signature: _____

Date: _____

Your signature above indicates that you understand the above conditions of participation in this research study and that you have had the opportunity to have your questions answered by the project researchers.

I would like to receive a copy of the scientific report of this research: □ Yes □ No
I would like to receive a one page summary report of this research: □ Yes □ No

If yes, I would like to receive this by:

□ **Email** _____

□ **Mail** _____

_____

_____

Copy of Consent for Participant - You are being given a copy of this informed consent to keep for your records

Why are we inviting you to participate in this project?

- We know that many people find it hard to understand food labels. Your participation as a volunteer in this project will help us learn how to make food labels easier for people to understand and use.

Why are we doing this project?

- There are new types of packaged foods in stores. These foods have much higher levels of added vitamins and minerals and other ingredients such as caffeine and herbals (for example: ginseng). These foods need to include directions for their proper use on the food label. Some will be required to carry caution statements to ensure that they are being used appropriately by consumers.
- We want your input to determine how best to label these new types of foods so that you can tell these foods apart from other packaged foods.
- We also want your input to determine how to best label these foods with directions for their proper use.

How will we do this?

- You will be interviewed by one of the project researchers. She will ask you to look at examples of food labels for these new types of packaged foods.
- The researcher will then ask you questions about the food labels, such as what label information helps you notice that these foods are different from other packaged foods and what label information best helps you understand their directions for proper use.
- The interview session will take about 45 minutes and will be audio-recorded. These audio recordings will be written-out and saved as an electronic document. The audio-recordings will then be erased.

Where will we be doing these interviews?

- Interviews will be held in private meeting rooms at locations closest or most convenient to you, including Ottawa University and local community centres.

Can I be in the project?

Yes, you can if….

- You are willing to take part in the individual interview.
- You can speak and read French or English.
- You are at least 18 years old.
- You can understand everything on this page.

You also have to be part of one or more of the following groups:

- You are 50 years or older.
- You are involved in 60 minutes a day of physical activity including at least 3 times a week of vigorous physical activity.
- You have children living at home under 18 years of age.

What if I start the project and then want to stop? Can I do that?

- Yes. Once you start the project, you can stop at any time. You won't have to explain why you want to stop.
- If you decide to stop, all of the interview information we have collected from you, including the audio-recording, will be kept and used for the purpose of this research.

Are there any risks to being in the project?

- Answering questions about food labels can be hard. It requires reading the labels plus some math and a little writing.
- Some people may feel uncomfortable having their interview recorded.

Do I get any benefit from being in the project?

- There are no direct benefits to you for being in the project but you will be helping us learn how to make food labels better.

Privacy

- The only thing that will have your name on it will be this consent form and the recruitment screening form. We will lock these in a file cabinet and no one will see these except the research staff. Files will be kept for a period of 7 years once the study has been completed.

Compensation

- You do not get paid for being in the project however the project researcher doing the interview will provide you with a $25 food voucher to use at a local grocery store at the end of the interview. If you decide to withdraw from the study partway through the interview, you will still be given the food voucher.
- If you use the bus to get to and from the interview the project researcher will give you bus tickets at the end of the interview.
- We can reimburse you up to a maximum of $15 if you need to pay for a taxi, parking or child-care to be able to take part in the interview session. You will need to give the researcher your receipts as proof of payment so that you can be reimbursed.

What will we do with the results of the project?

- The results of this study will be used to develop new labeling research tools that will be used at a later date with other participants.
- The results will also be included in a research report and presentation by Rana Wahba as part of her Master's degree in Health Sciences at the University of Ottawa.
- We will share the results of the project by telling about them at research meetings. The results will also be written up in a research report and published in a scientific journal. Your name will not be used in any of these documents.
- When the project is over, we can send you a copy of the scientific report and a one page summary report if you give us your contact information (email or mailing address).

Your Rights

- You might have questions about your rights as a person in this project. You might also want to confirm that this project has been approved and is safe for you to be in.

- If you have any questions about this research, you can contact:
  Elizabeth (Beth) Mansfield, Health Canada
  Telephone: 613-957-3841
  Email: beth.mansfield@hc-sc.gc.ca

- If you have questions about your rights as a research participant, you may contact:
  Manager, Research Ethics Board of Health Canada
  Telephone: (613) 941-5199
  Email: REB-CER@hc-sc.gc.ca
  or

Human Research Ethics Program
Telephone: (416) 946-3273
Email: ethics.review@utoronto.ca

Privacy Notice

The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to conduct the research project "Consumer Competencies with Label Information on Supplemented Foods in Canada" under Section 4 of the Department of Health Act.

Purpose of collection: We require your personal information to determine your eligibility and record your consent to participate in this research study that will inform labelling policy, guidance documents, and development of labelling tools for supplemented foods. If you request a copy of the research study, your contact information will be used to provide one to you.

Other uses or disclosures: Your personal information will not be shared. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

For more information: This personal information collection is described Health Canada's Health Related Research class of personal information, in Info Source, available online at infosource.gc.ca.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at 613-948-1219 or privacy-vie.privee@hc-sc.gc.ca . You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Appendix H: Discussion Group Consent Form

Nutrition Labelling Research Project
Information and Consent Form for Discussion Groups

Project Researchers:

Elizabeth (Beth) Mansfield, PhD, RD, Health Canada, Ottawa, Ontario
Elaine de Grandpre, MHSc, RD, Health Canada, Ottawa, Ontario
Doris Gillis, PhD, RD, St Francis Xavier University, Antigonish, Nova Scotia
Mary L'Abbé, PhD and Alyssa Schermel, MSc, University of Toronto, Toronto, Ontario
Rana Wahba, BSc Dietetics, Master's Student, University of Ottawa, Ottawa, Ontario

Organizations:

Bureau of Nutritional Sciences, Food Directorate, Health Canada, Ottawa, Ontario
Department of Nutrition, St Francis Xavier University, Antigonish, Nova Scotia
Department of Nutritional Sciences, University of Toronto, Toronto, Ontario
Department of Health Sciences, University of Ottawa, Ottawa, Ontario

Participant Name: _____

Assigned Group ID: _____

Signature: _____

Date: _____

Your signature above indicates that you understand the above conditions of participation in this research study and that you have had the opportunity to have your questions answered by the project researchers.

I would like to receive a copy of the scientific report of this research: □ Yes □ No

I would like to receive a one page summary report of this research: □ Yes □ No

If yes, I would like to receive this by:

□ **Email** _____

□ **Mail** _____

_____

_____

Copy of Consent for Participant - You are being given a copy of this informed consent to keep for your records.

Why are we inviting you to participate in this project?

- We know that many people find it hard to understand food labels. Your participation as a volunteer in this project will help us learn how to make food labels easier for people to understand and use.

Why are we doing this project?

- There are new types of packaged foods in stores. These foods have much higher levels of added vitamins and minerals and other ingredients such as caffeine and herbals (for example: ginseng). These foods need to include directions for their proper use on the food label. Some will be required to carry caution statements to ensure that they are being used appropriately by consumers.
- We want your input to determine how best to label these new types of foods so that you can tell these foods apart from other packaged foods.
- We also want your input to determine how to best label these foods with directions for their proper use.

How will we do this?

- We will ask you to take part in a discussion group with other people.
- One of the researchers will lead this discussion group. She will ask you to look at examples of food labels for these new types of packaged foods.
- The researcher will ask you to discuss what label information helps you notice that these new foods are different from other packaged foods and what label information best helps you understand their directions for proper use.
- The discussion group session will take about 60 minutes and will be audio-recorded. The audio recording will be written-out and saved as an electronic document. The audio-recordings will then be erased.

Can I be in the project?

Yes, you can if….

- You are willing to take part in the discussion group.
- You can speak and read French or English.
- You are at least 18 years old.
- You can understand everything on this page.

You also have to be part of one or more of the following groups:

- You are 50 years or older.
- You are involved in 60 minutes a day of physical activity including at least 3 times a week of vigorous physical activity.
- You have children living at home under 18 years of age.

What if I start the project and then want to stop? Can I do that?

- Yes. Once you start the project, you can stop at any time. You won't have to explain why you want to stop.
- If you decide to stop, all of the information we have collected from you, including the audio-recording, will be kept and used for the purpose of this research.

Are there any risks to being in the project?

- Answering questions about food labels can be hard. It requires reading the labels plus some math and a little writing.
- Some people may feel uncomfortable having their discussion group recorded.

Do I get any benefit from being in the project?

- There are no direct benefits to you for being in the project but you will be helping us learn how to make food labels better.

Privacy

- We encourage you to keep all the information shared in the discussion group confidential however we cannot guarantee confidentiality.
- Only project researchers will have access to the discussion group information we will be collecting.
- The only thing that will have your name and personal information on it will be the screening and consent forms that you will sign and the recruitment screening form. We will lock these in a file cabinet and no one will see these except the research staff.
- All research information will be kept for a period of 7 years once the study has been completed.

Compensation

- You do not get paid for being in the project however we will provide you with a $25 food voucher to use at a local grocery store after you have completed the discussion group. If you decide to withdraw from the study partway through the discussion, you will still be given the voucher.
- If you use the bus to get to and from the interview the project researcher will give you bus tickets at the end of the interview.
- We can reimburse you up to a maximum of $15 if you need to pay for a taxi, parking or child-care to be able to take part in the interview session. You will need to give the researcher your receipts as proof of payment so that you can be reimbursed..

What will we do with the results of the project?

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- The results of this study will be used in a research report and presentation by Rana Wahba for her Master's degree in Health Sciences.
- We will also share the results of the project by telling about them at research meetings. The results will also be written up in a research report and published in a scientific journal. Your name will not be used in any of these documents.
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  Email: beth.mansfield@hc-sc.gc.ca

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Telephone: (613) 941-5199
Email: REB-CER@hc-sc.gc.ca
or
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