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A risk-based labelling strategy for supplemented foods in Canada: consumer perspectives

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Abstract

Unlike conventional foods, supplemented foods are prepackaged foods containing one or more added supplemental ingredients, such as vitamins, mineral nutrients, amino acids, and caffeine, which have historically been marketed as providing specific physiological benefits or health effects. These ingredients can pose a health risk if overconsumed by the general population or if consumed by certain vulnerable populations such as children or those who are pregnant. Consumer perspectives of a proposed risk-based multicomponent supplemented food labelling strategy to protect the health and safety of Canadians were explored using virtual discussion groups with participants ($n = 88$) of varying socio-demographics and health literacy levels. Thematic content analysis of the discussions was conducted using core health literacy competencies of accessibility, understanding, and appraisal of the risk-based product labelling information. The front-of-package supplemented food caution identifier was attention grabbing and conveyed a message to search out and carefully consider the Supplemented Food Facts table and cautionary labelling elements on the back of the package. These back-of-package labelling elements enhanced awareness of the supplemental ingredients and the specific cautions for use of the supplemented food. This risk-based product labelling strategy, with multiple components, was perceived to be a useful strategy for distinguishing supplemented foods from conventional foods and enhancing awareness of the cautionary labelling. Educational strategies will be required to ensure that the health and safety risks associated with supplemented foods are understood so that consumers can make more informed consumption decisions.

Novelty

- Risk-based labelling strategy for supplemented foods
- Strategy goes beyond the general requirements for prepackaged foods

Key words: supplemented foods, risk-based, cautionary labelling

Introduction

In the Canadian marketplace in recent years, pre-packaged foods with supplemental ingredients such as vitamins and mineral nutrients, amino acids, and caffeine have been marketed as providing specific physiological benefits or health effects. These "Supplemented Foods" (SFs) differ from fortified foods that have added vitamins and mineral nutrients for an established public health purpose. SFs also differ from conventional foods and some may not be suitable for ad libitum consumption due to the potential risks associated with overconsumption of the supplemental ingredients or if consumed by certain sensitive or vulnerable sub-populations (e.g. children or those who are pregnant). Since SFs are sold alongside conventional foods and currently lack product labelling features that clearly differentiate them and their potential risks, there is potential for confusion among consumers as to the safe use of these products.

In 2021, Health Canada published a proposed regulatory framework for SFs (Government of Canada 2021). The proposed regulations outlined detailed conditions for the use of supplemental ingredients in food to protect the health and safety of people. The proposal also established additional requirements on risk-based labelling of SFs, which goes beyond the general requirements for prepackaged foods. In order for consumers to make risk-based decisions regarding personal use of SFs, the product labelling must make it easy for consumers to identify an SF, and it must show how SFs are different from conventional foods, including the type and amount of the supplemental ingredients and cautionary labelling when required. Furthermore, this risk-based cautionary labelling must be easily accessible and understood to ensure that consumers are aware of any potential risks for health and safety if the particular SF is overconsumed by the general population or if consumed by certain vulnerable populations.

Health Canada's proposed risk-based labelling measures are unique to SFs. As it would be inappropriate to maintain the "Nutrition Facts table" when the supplemental ingredients present in SFs go beyond nutritional value (e.g. caffeine and other bioactive non-nutritive ingredients), these labelling measures consist of a front-of-package (FOP) SF caution identifier; a back-of-package (BOP) SF Facts table containing a distinct "Supplemented with" section for declaration of supplemental ingredients; and specifications for BOP cautionary labelling to ensure safe use of these products (Government of Canada 2021). Based on the publicly available lists for SFs, including caffeinated energy drinks (CEDs), which have been issued Temporary Marketing Authorization (TMA) Letters (Government of Canada 2023), 100% of the CEDs and approximately 60% of the SFs would require cautionary labelling.

While federally regulated nutrition labelling currently available on pre-packaged foods is a key source of nutrition information to make informed food choices (Goodman et al. 2011; Government of Canada 2013), many Canadians face challenges in accessing, understanding, and evaluating food label information (Campos et al. 2011), in particular those who may be disadvantaged by risks of limited health literacy (Mansfield et al. 2020*a*). In addition, the nutrition labelling must ensure that consumers can make informed decisions for personal use. This consumer research will help elucidate consumer perceptions on accessibility, understanding, and appraisal of a risk-based multicomponent SF nutrition labelling strategy, including the utility of an SF caution identifier. It will also inform the SF regulatory framework and the development of educational strategies for these risk-based labelling measures to fulfill risk management and risk communication requirements for SFs.

Materials and methods

A Canadian-based contract research organization (CRO) specializing in the implementation of qualitative consumer research (Leger Inc., Montreal, QC) was contracted to implement the study.

Study sample and recruitment

Participants aged 14 years and older who had no links with food industry or Health Canada, who did not work in food and nutrition, and who had not worked previously in market research were eligible to participate. The CRO recruited a convenience sample of participants from across Canada using their market research panels through email and telephone. Participants needed to have access to a computer with high-speed Internet connection, a webcam, and a microphone to be included in the study. The CRO engaged a Northern recruitment partner who has a large Northern Canadian consumer market research for the recruitment of Aboriginal peoples from the Northwest Territories, Yukon and Nunavut. Given the limitations of the lack of high-speed Internet in some areas of the territories, recruitment was mostly located in the most urbanized areas of the territories. In the first step of the eligibility screening, participants completed the Canadian adaptation of the Newest Vital Sign, a screening tool for health literacy (Mansfield et al. 2018).

Research ethics and consent

The study was conducted according to the Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans, which sets the standard for research ethics boards in Canada. The protocol of this study was approved by Health Canada's Research Ethics Board for Human Research (REB 2020-034H). All participants provided written informed consent before assignment into discussion groups.

Study design and setting

Twelve virtual (online) discussion groups with Canadians of varying socio-demographics and health literacy levels were used to generate consumer perceptions and insights on awareness, understanding, appraisal, and use of the proposed multi-component SF labelling strategy. Discussion groups were stratified by health literacy level in order to minimize the known risks of stigmatization when discussing the complexities of numeric and prose-based label information and to ensure an open discussion across participants (Easton et al. 2013). This also ensured that the facilitator communicated at an appropriate level for marginalized groups. All discussion groups were audio- and video-recorded so that content analysis could be conducted. All discussion groups took place in January and February 2021. Duration of the discussion groups was approximately 60 min.

Table 1 describes the specific characteristics and distribution of each group. All participants in the discussion group received $100 as compensation. Indigenous peoples in the northern territories were offered $150 for their participation, given the difficulty in recruiting and in securing their participation on the dates established for these groups.

Study procedures

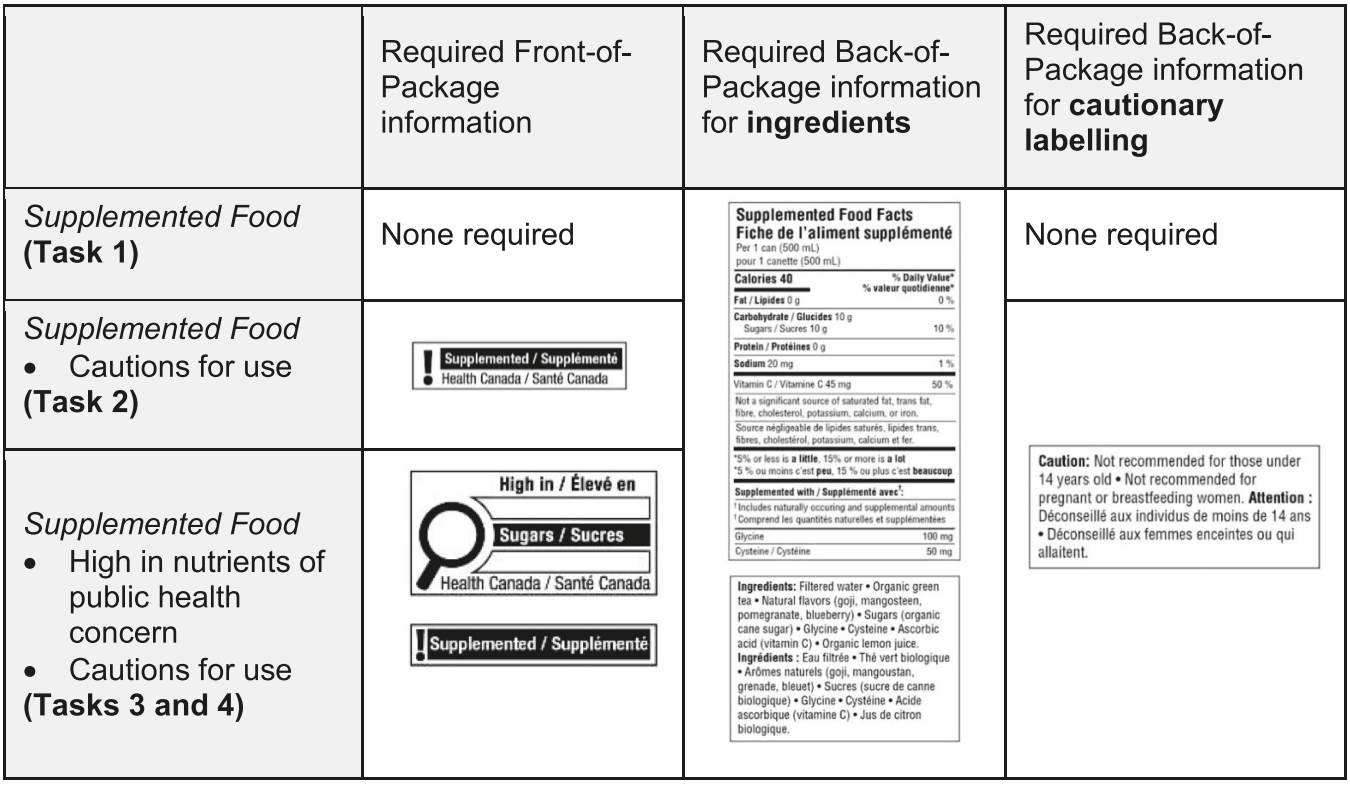
Moderators from the CRO facilitated the discussion groups using a virtual moderation platform and a discussion group guide developed and pilot-tested by Health Canada researchers (EM, RW, EDG) with expertise in social and behavioural research and experience in designing, implementing, and analyzing consumer research with a health literacy lens (Mansfield et al. 2020*a*). As part of the introduction to each discussion group, the moderator introduced participants to the concept of SFs and the nutrition labels that Health Canada had developed to help Canadians identify these foods and distinguish them from regular foods and provide guidance on appropriate and safe use of these products. The moderator stated that Health Canada wanted feedback on these nutrition labels to help Canadians make informed SF choices. Participants then completed a series of four task-based virtual activities, designed to introduce the multi-component SF labelling approach, using a series of virtual representations of SF mock-packages highlighting the front and back of package label conditions (Fig. 1).

The preliminary online task introduced participants to virtual representations of an SF mock-package containing supplemental ingredients not requiring any cautionary labelling.

Table 1. Discussion group characteristics.

Session detail	Recruited participant	Participants in attendance	Language
Session 1—Primary grocery shopper with marginal health literacy	8	7	English
Session 2—Primary grocery shopper with adequate health literacy	8	8	English
Session 3—Primary grocery shopper with marginal health literacy	8	8	French
Session 4—Youth 14–17 with adequate health literacy	8	8	English
Session 5—Youth 14–17 with marginal health literacy	8	8	English
Session 6—Youth 14–17 with adequate health literacy	8	8	French
Session 7—Pregnant or breastfeeding women with marginal health literacy	8	8	English
Session 8—Pregnant or breastfeeding women with adequate health literacy	8	8	English
Session 9—People with chronic health condition with marginal health literacy	8	7	English
Session 10—People with chronic health condition with adequate health literacy	8	7	English
Session 11—Indigenous in Northern Territories with marginal health literacy	8	6	English
Session 12—Indigenous in Northern Territories with adequate health literacy	8	5	English

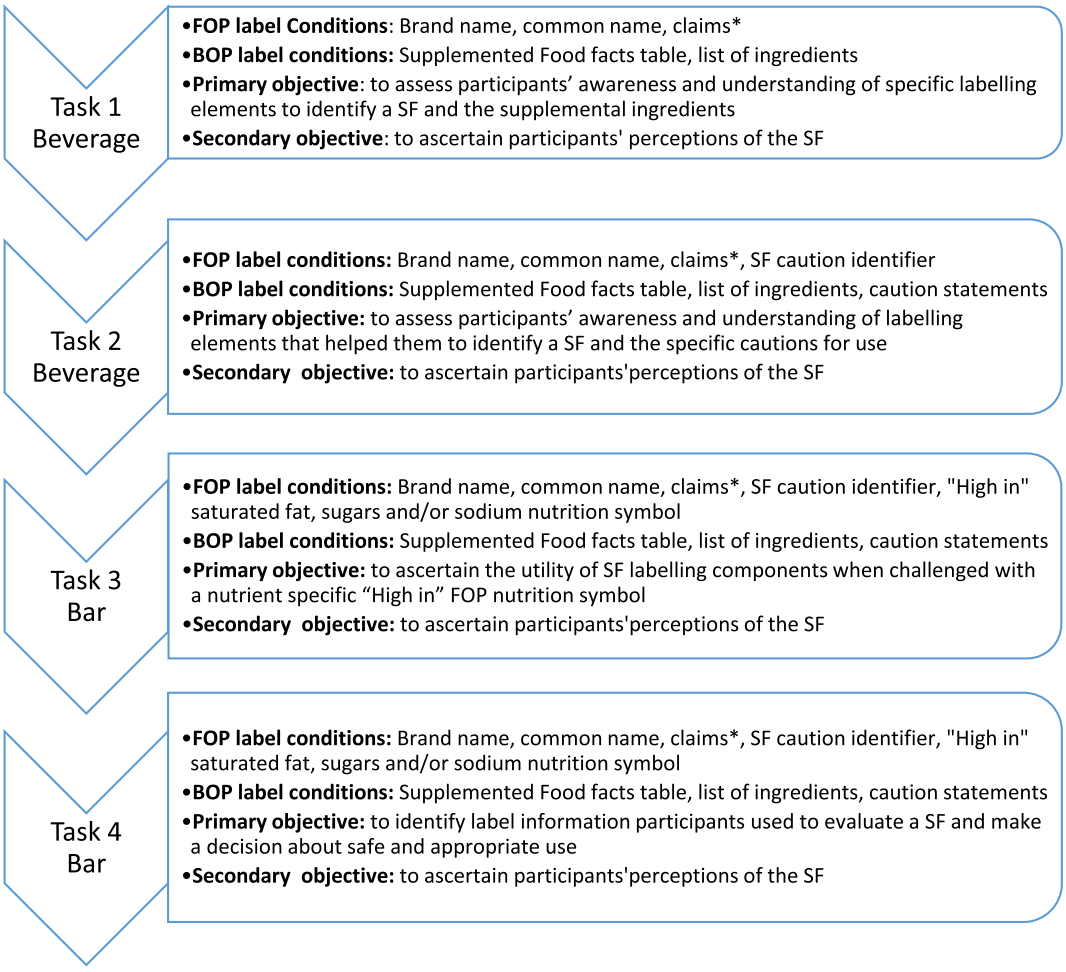
Fig. 1. Required supplemented food (SF) labelling components for tasks 1–4.**Required back-of-package (BOP) information depends upon the nature of the supplemental ingredients and their cautions for use (if applicable). All SF will require the SF Facts table and list of ingredients. Only those SFs that have supplemental ingredients with cautions for use are required to include the front-of-package (FOP) SF caution identifier and the BOP cautionary labelling box.



Task 2 introduced participants to virtual representations of an SF mock-package with supplemental ingredients requiring cautionary labelling. Tasks 3 and 4 introduced participants to virtual representations of SF mock-packages high in nutrients of public health concern (saturated fat, sugars, and/or sodium) and containing supplemental ingredients requiring cautionary labelling (Fig. 1). Each task introduced virtual representations of increasingly more complex SFs and their requisite labelling requirements.

Each of the labelling tasks, their specific SF mock package labelling conditions, and key objectives are presented in Fig. 2. The moderator used the share screen function to show participants the entire mock-package, the front and back of the package as well as a series of zoomed-in images to support

Fig. 2. Labelling tasks, front-of-package (FOP) and back-of-package (BOP) mock-package labelling conditions, and key objectives. *Health claims, nutrient content claims, and marketing claims were present on the front of pack of all mock-packages.



the ensuing task-based discussions (refer to Appendix A for visuals). At the end of each discussion group, participants completed an online survey to evaluate their overall perceptions of SFs and the utility of the multi-component risk-based labelling approach to communicate the safe use of these products.

Data analysis

The virtual moderation platform software generated digital transcriptions that were reviewed for accuracy by bilingual research team members. A deductive content analysis approach was used to classify the data using five predetermined dimensions of labelling effectiveness (awareness, design factors, understanding, appraisal, and behaviour) (Sorensen et al. 2012). Researchers (RW, JL, and EM) coded the first discussion group independently and then regrouped to come to an agreement on application of the coding criteria. Researchers (RW and JL) then applied the coding strategy independently to the remaining discussion groups using the NVivo 11 Software (QSR International Pty Ltd. 2015). Participant responses to the survey questions are presented as frequency counts and percentages (Table 4).

Results

Awareness and understanding of the FOP labelling elements

Participant awareness and understanding of the proposed FOP labelling elements for SFs are outlined in Table 2.

When challenged with SF products that did not require cautionary labelling or were not high in nutrients of public health concern, participants initially interacted with the FOP, noticing and using the voluntary industry labelling elements, such as the company name, brand name, claims, and highlighted ingredients to identify the products as an SF. When challenged with an SF bearing the proposed SF caution identifier, the presence of the exclamation mark was attention grabbing. Some participants used it to confirm that the product was an SF while others were not sure what the presence of the SF caution identifier actually meant. The SF caution identifier did caution some to consider the product in more detail by going to the BOP to access more information (Table 3). The Health Canada attribution in the SF caution identifier conferred mixed meanings of Health Canada's role, ranging from a recommendation, regulatory approval, and product endorsement to product safety. When participants were

Table 2. Participants' awareness and understanding of front-of-package (FOP) labelling elements for supplemented foods (SF).

FOP labelling elements	Awareness and understanding of FOP labelling elements	Utility of FOP labelling elements
Industry branding	• *"Just to the side it says the name of the company, Empower Inc., suggesting that something particular has been added."* • *"It says Vitamin Boost. That, to me suggests that it's supplemented."*	• Attracts attention • Identifies an SF
SF caution identifier	• *"But then another thing that really stood out was at the top where there's the exclamation mark and it says supplemented Health Canada."* • *"And I'd certainly look at the back more carefully when I saw that."* • *"It says, supplemented with the exclamation mark. Maybe that means something. I really don't know what that means."* • *"I think it would be better if it's something that Health Canada is very concerned about, that something under that exclamation point or something, like "read the back label for more."*	• Attracts attention • Identifies an SF • Cautions to look at the BOP for more information on use • Lack of meaning for exclamation mark • Should highlight the risk-based information
Health Canada attribution in the SF caution identifier	• *"I haven't really seen the Health Canada label on a food product that looks like this. So I'm assuming that it looks like it's categorized as a supplemented food by Health Canada."* • *"It must be recommended by Health Canada to be supplemented with whatever is in it."* • *"Health Canada, I guess, approves it so it must be good."* • *"It's gone through a lot of research by Health Canada. They looked into this."* • *"It's okay for me to intake. It's been checked up on."*	• Confers varied understanding of Health Canada's role
"High in" nutrition symbol	• *"That's almost like a warning, which I'm not used to on most foods."* • *"Health Canada label in the very front with little magnifying glass is drawing your attention to the fact that it's really high in sugar."* • *"But this one's kind of showing me "take a look at the sugars at the back of the label."*	• Attracts attention • Refocuses onto the nutritional attributes of the food • Encourages access of the back of package for more nutrition information

further challenged with an SF, which not only required cautionary labelling but was also "High in" nutrients of public health concern (i.e. saturated fat, sugars, and sodium), participants re-focused their attention to the nutritional attributes of the food. The presence of the "High in" FOP nutrition symbol encouraged some to access the BOP for more nutrition information. The combination of the SF caution identifier and the "High in" FOP nutrition symbol with cautionary labelling on the BOP convinced most participants that the SF was not an appropriate food choice, despite what they perceived the package design, FOP claims, Health Canada attribution, and brand name might be trying to convey.

Awareness and understanding of the BOP labelling elements

The SF Facts table's large, bold font heading "**Supplemented Food Facts**" attracted participants' attention and the supplemental ingredient footnote: "including naturally occurring and supplemental amounts" confirmed the type of supplemental ingredients. When asked to identify the type of supplemental ingredients participants used various labeling elements including the FOP claims, FOP highlighted ingredients, and the "Supplemented with" section of the SF Facts table. The lack of familiarity of many of the supplemental ingredients confused some of the participants. In addition, the lack of %Daily Values for supplemental ingredients in the SF Facts table made it challenging for participants to evaluate the significance of the amount of each supplemental ingredient and use the information to make an informed decision about the SF.

The unfamiliarity with the presence of cautionary labelling on foods made it challenging for participants to engage with that information. Nonetheless, the cautionary labelling did attract attention when participants interacted with the BOP of the SF products. When noticed, cautionary labelling was considered by some to be helpful information to have. Cautionary labelling was not easily accessible due to its position on the BOP especially when pressed for time or motivation to search for that information. When the cautionary labelling was placed under the packaging flap (i.e. on a bar), it was even more challenging to access and thus be aware of. Some participants interpreted the BOP placement of cautionary labelling as signaling that it was not as important as the FOP label information. Participants expressed mixed feelings on the intent of the cautionary labelling statements and the overwhelming amount of information to take into consideration to put the cautions into action. The lack of a specific rationale or intent of the cautionary labelling made it challenging to know if consumption limits expressed in the cautionary labelling were related to the amount of supplemental ingredient or some other ingredient. This also led some to question the credibility of cautionary labelling without a rationale. While some cautionary labelling statements were considered to be alarming in nature, the varied assortment of cautionary statements were generally perceived to

Table 3. Participants' awareness and understanding of back-of-package (BOP) labelling elements for supplemented foods (SF).

BOP labelling elements	Awareness and understanding of BOP labelling elements	Utility of BOP labelling elements
SF Facts table	• *"Well, on top of the label there it says "supplemented food facts, so it's labeled on the back of the can."* • *"On the back, within the nutritional information at the bottom of the supplemented food facts, it includes the naturally and occurring supplemental amounts, the supplemented with, that section there, and it gets more specific of what it's supplemented with."* • *"Because the percentages for the vitamin A etcetera are not there, how that might interact, or add to what you"re taking a supplement for your pregnancy or if you"re breastfeeding or if you're on any other kind of vitamin, for that matter. So, it's sort of like it's half of the information you need to really make an educated decision."*	• Attracts attention • Identifies an SF • Identifies type and amount of supplemental ingredients • Lack of %DV for supplemental ingredients challenges decision-making
Cautionary labelling	• *"And one thing about the back I noticed on this product that says "not recommended for those under 14 or for pregnant or breastfeeding women" and so that I think is very helpful."* • *"For most of the foods that I've seen I haven't really noticed labeling such as that, but I think it's a very positive thing. And the more information that us as consumers have before we make these decisions to purchase, the better."* • *"So I am breastfeeding. I might accidentally pick this up and drink it because I don't have the time to read everything at the back."* • *"The caution label is on the back, but I feel like that is also because it's not that big of a deal. If there was a crazy big deal, they'd probably put it on the front because they don't want to hurt people or anything like that."* • *"And this [caution box on the BOP] seems like it should be more important. Like slap that on the front. Put it in orange, maybe."* • *"At the back when it's telling me about the cautions, do not consume with other supplements, again I mean, this is something you have to take into consideration. Do I take my vitamins, my multivitamins, and don't take this bar? Or should I eat this bar and forget about my other vitamins? I mean it's too much to take into consideration."* • *"I wouldn't take it, especially when it says don't take more than one a day, then that's a big, big red flag."* • *"It says not for pregnant people and for breastfeeding because it could like damage the baby or whatever."* • *"… if it's not recommended for kids and not recommended for pregnant women, it really can't be that good for you."* • *The only sort of thing that would make it better is if the producer of this product maybe had a web link there, that a person could get a little more detail about that."*	• Attracts attention • Provides needed information to make decisions • BOP placement limits accessibility • BOP deters from importance of cautionary labelling • Front-of-package placement would highlight importance of cautionary labelling • Overwhelming amount of information in cautionary labelling • Cautionary labelling is a warning about the SF • Cautionary labelling warns about the risks of SF consumption • Cautionary labelling suggests the SF is not good for you • Cautionary labelling could include web link for additional information

communicate a strong health caution. Specific design options for cautionary labelling, such as placement on the FOP and the use of colour, were suggested to highlight the awareness and importance of the cautionary labelling.

At the end of each discussion group, overall participant perceptions' of the SF multi-component labelling strategy were assessed with six multiple choice questions (Table 4). Overwhelmingly, participants acknowledged the utility of an SF cautionary identifier to identify an SF and over 90% perceived the SF Facts table as an indicator of the type and amount of supplemental ingredients. The vast majority interpreted the BOP cautionary labelling as guidance and cautions for use of the SF and to determine the relative healthiness of the food product.

As a final exercise, participants were polled on their overall perceptions of SFs (Fig. 3). The three questions and measures were developed for use in previous consumer research informing the development of the multi-component labelling approach for SFs (data not yet published). They were used in this research as a consistent measure of the utility of the labelling approach to inform consumer decision-making for safe and appropriate use of SFs, and to generate a sense of consumer perceptions of these new foods after interacting with a variety of SFs and their requisite labelling. While the label information was always (41%) or sometimes (51%) sufficient for participants to be able to make a decision for personal use, many perceived SFs to sometimes be good for them and sometimes be healthier than regular foods or beverages.

Discussion

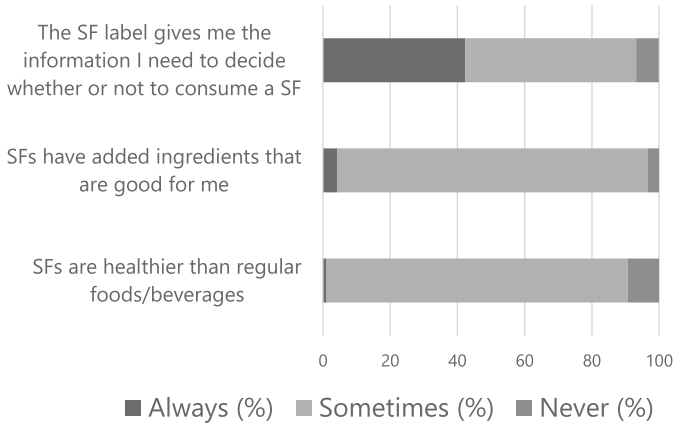
Fundamental to any nutrition labelling strategy are labelling components that consumers can engage with to be able to make informed food choices. These labelling components must catch consumers' attention, be easily understood, and appropriately evaluated by consumers in the context of their specific dietary goals and needs. For nutrition labels to be effective, the information provided should help guide consumers' food choices and decisions (Cecchini and Warin 2016). SFs are different from conventional foods in that they contain supplemental ingredients that can pose a risk to health if consumed in excess by the general population or

Table 4. Participant perceptions of the multi-component labelling strategy for supplemented foods (SF) (responses to the online survey; product labelling images in Appendix A).

Label element type of SF	Answer choice	Ranked responses *N* (%)
FOP SF caution identifier granola bar	This tells me that this bar is a supplemented food	82 (93.2%)
	This tells me that there is cautions of use for this bar	45 (51.1%)
	This tells me the type and amount of supplemental ingredients in this bar	11 (12.5%)
	This tells me that certain individuals should not eat this bar	8 (9.1%)
FOP SF caution identifier caffeinated energy drink	This tells me that this beverage is a supplemented food	87 (98.9%)
	This tells me that there are cautions about the use of this beverage	49 (55.7%)
	This tells me that Health Canada has approved this beverage	28 (31.8%)
	This tells me that certain individuals should not drink this beverage	10 (11.4%)
FOP "High in" fruit juice cocktail	This tells me that this beverage is an unhealthy beverage	79 (89.8%)
	This tells me that this beverage is a supplemented food	10 (11.4%)
	This tells me the type and amount of supplemental ingredients in this beverage	9 (10.2%)
	This tells me that it is a healthy beverage	1 (1.1%)
BOP SF Facts table granola bar	This tells me the type and amount of supplemental ingredients in this bar	84 (95.5%)
	This tells me that this bar is a supplemented food	64 (72.7%)
	This tells me how much of the bar I can eat	3 (3.4%)
	This tells me that certain individuals should not eat this bar	2 (2.3%)
BOP cautionary labelling granola bar	This tells me that certain individuals should not eat this bar	86 (97.8%)
	This tells me how much of the bar I can eat	64 (72.7%)
	This tells me that this bar is a supplemented food	36 (40.9%)
	This tells me the type and amount of supplemental ingredients in this bar	6 (6.8%)
BOP cautionary labelling caffeinated energy drink	This tells me that certain individuals should not drink this beverage	86 (97.7%)
	This tells me how much of this beverage I can drink	71 (80.7%)
	This tells me the type and amount of the supplemental ingredients in this beverage	11 (12.5%)
	This tells me that this beverage is a supplemented food	8 (9.1%)

Note: Back-of-package (BOP), front-of-package (FOP);

Fig. 3. Distribution of participant perceptions of supplemented foods (SF).



if consumed by vulnerable populations such as children or those who are pregnant. It is therefore important to ensure that the labelling strategy supports consumers' abilities to distinguish SFs from conventional foods, to understand the health risks associated with these products, and to make informed choices related to their safe consumption.

The design of the FOP SF caution identifier was based on label characteristics that are attention grabbing (Goodman et al. 2018; Reyes et al. 2019) and that facilitate awareness and understanding (Leger Inc. 2018; Mansfield et al. 2020*b*). Consumer research has highlighted the need for simple, clear FOP labelling attributes to help consumers distinguish between similar products without needing advanced calculation skills to decipher nutritional information on the BOP (Kleef and Dagevos 2015; de Morais Sato et al. 2019; Temple 2020). The black and white text-based SF caution identifier that is proportional to the size of the principal display surface of the package (i.e. the height and width of the identifier increases as the principal display surface increases) including a recognizable warning symbol (exclamation mark), a Health Canada attribution, and a perimeter that clearly differentiates the SF caution identifier from the rest of the FOP elements was easily accessed and used by participants to identify an SF that had cautions for use. In situations where consumer understanding, time, and/or motivation are lacking to search out and pay attention to the specifics on the BOP, the noted heuristic processing of the FOP SF caution identifier as a warning message by participants could play an important role (Leathwood et al. 2007). Together, the SF caution identifier design characteristics and the inclusion of Health Canada (i.e. government) attribution (Vyth et al. 2009; Acton et al. 2018) have been shown in FOP research to be fundamental

for effectiveness (Reyes et al. 2019; Taillie et al. 2020). The Health Canada attribution enhanced the credibility of the SF caution identifier, as has also been observed with other types of FOP nutrition labels on conventional foods (Acton et al. 2018). Participant understanding ranged from regulatory approval, recommendation, or an endorsement of the supplemental ingredients by Health Canada, which is not surprising as the public sees Health Canada as the source of credible information on food labels (i.e. FOP label, Nutrition Facts table, and list of ingredients). In previous research conducted with a never before seen or used "High in" front-of-package warning label on foods high in nutrients of public health concern, approximately one in two participants thought that the Health Canada attribution as part of the FOP warning label made them trust the symbol and told them who was responsible for the label (Leger Inc. 2018). Consumer awareness and education campaigns will no doubt be required to assist consumers of varying health literacy levels to better understand and evaluate the labelling components of SFs, including the SF caution identifier and the Health Canada attribution, to be able to make more informed decisions on appropriate use of SFs.

The SF Facts table on the BOP was easily accessed and used by most participants to find the type and amount of supplemental ingredients in the food products. Some of these supplemental ingredients, such as commonly used vitamins (e.g. Vitamin D) and mineral nutrients (e.g. calcium), were relatively well known among participants. However, the wider range of supplemental ingredients used in the SFs did not have the same level of consumer nutritional awareness. This made it challenging for participants to consistently recognize the link between the supplemental ingredients and specific cautionary labelling. The wording of the supplemental ingredient footnote "includes naturally occurring and supplemental amounts" was not well understood and, in combination with the absence of %Daily Values for the supplemental ingredients, limited participants' understanding and evaluation of the absolute amount of each supplemental ingredient to be able to rationalize their decision for use. Educational strategies will be required to improve consumers' supplemental ingredient nutritional knowledge as this will affect their future usage of the labelling information to make more informed decisions on safe use of these SFs.

The cautionary labelling statements were developed to convey important risk-based supplemental ingredient information for safe use of SFs and to be useful for those at the greatest risk of limited/marginal health literacy. Overall, participants considered cautionary labelling statements to be critical pieces of information that conveyed strong and important health warnings, despite their BOP placement leading some participants to have mixed feelings about their relative importance and intent. The lack of specific rationales explaining each of the cautionary labelling statements' risk to health made it challenging for participants to know if consumption limits were related to the amount of the supplemental ingredient or to some other ingredient.

Overall, participants of varying health literacy levels and socio-demographics perceived SFs to have varying degrees of healthiness compared to regular foods and to contain supplemental ingredients that could be good for them. This judgement of healthiness, based on the presence of nutrition-related FOP label claims and the presence of supplemental ingredients such as vitamins/mineral nutrients, provides evidence of a "health halo effect" (Roe et al. 1999). A small body of research suggests that there is potential for consumption patterns to be shifted to include more of certain food categories if they are "fortified" with vitamins and mineral nutrients (Kalergis and MacDonald 2009) including overconsumption of ingredients that may not be appropriate for an age or gender group (Provencher and Jacob 2016). The addition of vitamins and mineral nutrients to foods of otherwise poor nutritional value has been seen to be an "added bonus" among some Canadian parents (Western Opinion Research 2004). In addition, if SFs are perceived as healthier, it raises concerns surrounding the potential to lead to nutrient imbalance and/or high intakes approaching or exceeding Tolerable Upper Intake Levels if other nutritional attributes of the food are not taken into consideration (Tarasuk 2014). One of the novelties of this research is how consumers will evaluate SFs that also carry the "High in" FOP nutrition symbol. Interestingly, the addition of a "High in" FOP nutrition symbol on an SF re-focused participants' attention to the nutrients of public health concern and appeared to mitigate this halo effect, as has been seen in other Canadian research with consumers of varying health literacy levels (Franco-Arellano et al. 2020). All of these findings will support informed action on educational messaging to improve consumers' competencies to access, understand, appraise, and use label information on SFs in order to make food choices consistent with their particular dietary goals/needs.

While it is known that attention given to nutrition information on conventional foods varies across consumer groups, situations, types of food products, package placement and number of labelling elements, these differences can be related to conflicting preferences for ease of use, being fully informed, and not being pressured into behaving in a particular way (Grunert and Wills 2007; Moreira et al. 2019; Meijer et al. 2021). With the advent of these new foods on the market in combination with a novel risk-based multi-component labelling approach, an effective SF awareness and education campaign will require a focus not only on the nutrition information being conveyed, but also on the varied contexts in which consumers engage with it. In addition, all SF information strategies and health communications will need to adopt a health literate approach so as to minimize consumer confusion and positively influence SI awareness and understanding. This is important for those people living in Canada with limited or no language proficiency in English or French, those disadvantaged by risks of limited/marginal health literacy, and those from cultural backgrounds with little awareness of these types of supplemental ingredients and their requisite cautionary labelling.

Limitations of this study include the non-probability-based sample, which was not representative of the Canadian population. Qualitative research does not produce generalizable results for the population. Since participants are invited to share ideas in a group setting, some individuals may be in-

fluenced to respond in similar ways as their counterparts. However, the targeted recruitment strategy produced a diverse sample to ensure socio-demographic differences in consumer perceptions. We also recruited specifically from the Northwest Territories, Yukon and Nunavut, a geographical area that is often excluded from this type of consumer research. An additional strength is that we screened all participants for health literacy so that we could stratify the discussion groups by health literacy level to minimize risks of stigmatization and to ensure an open discussion across participants. While the use of an online platform to conduct the labelling tasks and discussions does not represent a real-world scenario, participants interacted with the proposed SF labelling strategy exhibited on a variety of mock packages that do not exist in the marketplace to ensure a common ground for discussion and prevent any a-priori branding influence.

Conclusion

Unlike conventional foods, SFs contain supplemental ingredients that can pose a risk to health if they are consumed in excess by the general population or if consumed by vulnerable populations such as children and those who are pregnant. This risk-based labelling framework for SFs supports consumers in their ability to distinguish SFs from conventional foods, understand the health risks associated with these products, and make more informed choices related to their consumption. This research supports the application of a multi-component labelling approach that can be applied consistently across all SFs. In tandem with a comprehensive awareness and education strategy, this labelling strategy will help protect the health and safety of Canadians by reducing the risks of overconsumption of SFs within the general population and risks of exposure within vulnerable groups.

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Data generated or analyzed during this study are not available due to the confidential regulatory government business nature of this research.

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Competing interests

EM has received speaker fees and travel honoraria from Dairy Farmers of Canada, NovoNordisk, and InBody Canada. EM has received health care equipment from InBody Canada. RW, JL, and EDG declare there are no competing interests.

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Appendix A. Mock-packages by task

Mock-packages for six questions on participant perceptions of the mulit-component labelling strategy for Supplemented Foods (Table 4)

Task 1. Elan VitaMin BOOST—Youth and women (pregnant and breastfeeding groups). Front-of-package (FOP) label elements: brand name "VitaMin Boost," marketing claim "refreshing," common name "water beverage with vitamins and minerals," nutrient/health claims "Source of vitamin D and magnesium, vitamin D and magnesium help build bones and teeth." Back-of-package (BOP) label elements: Supplemented Food Facts table, list of ingredients.

Task 1. Elan VitaMin BOOST—General audience (remaining groups). Front-of-package (FOP) label elements: brand name "VitaMin Boost," marketing claim "flavoured with ginseng," common name "water beverage with vitamins and minerals," and nutrient/health claims "contains pantothenate and magnesium, factors in energy metabolism and tissue formation." Back-of-package (BOP) label elements: Supplemented Food Facts table and list of ingredients.

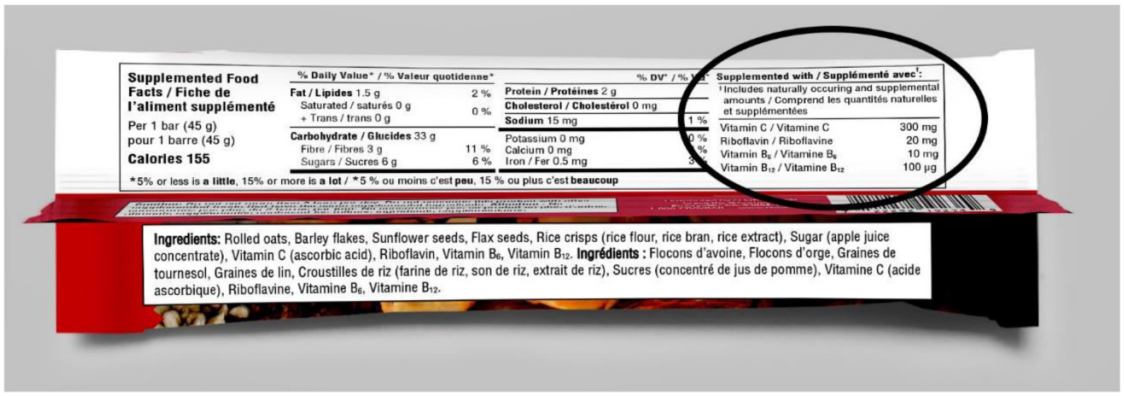
Task 2. BURST beverage—all groups. Front-of-package (FOP) label elements: brand name "Burst," Supplemented Food cautionary identifier that includes an exclamation mark, the word supplemented and the words "Health Canada," common name "Fruity green tea beverage," nutrient/health claims "High in Vitamin C, an antioxidant that helps protect your cells." Back-of-package (BOP) label elements: Supplemented Food Facts table, caution box, and list of ingredients.

Task 3. CRAVE bar—all groups. Front-of-package (FOP) label elements: brand name "Crave," marketing claim "Oats and Honey," a nutrition symbol that includes a magnifying glass, the words "high in sugars" and the words "Health Canada," Supplemented Food cautionary identifier that includes an exclamation mark and the word supplemented, nutrient/health claims "Source of vitamin C, a dietary antioxidant." Back-of-package (BOP) label elements: Supplemented Food Facts table, caution box, and list of ingredients.

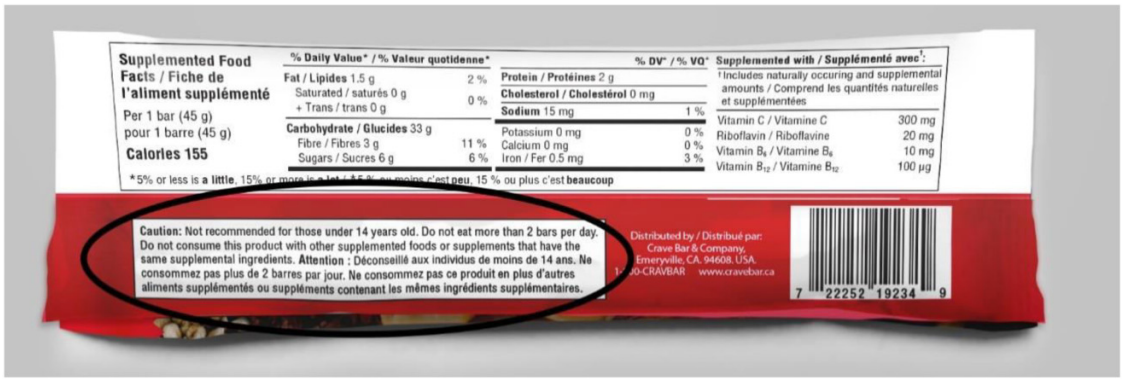
Task 4. CRAVE bar—all groups. Front-of-package (FOP) label elements: brand name "Everton's Chocobar," marketing claim "Sweet & Energizing," a nutrition symbol that includes a magnifying glass, the words "high in sat fat and sugars," and the words "Health Canada," Supplemented Food cautionary identifier that includes an exclamation mark and the word supplemented, claim "High caffeine content." Back-of-package (BOP) label elements: Supplemented Food Facts table, caution box, and list of ingredients.

Question 1. Front-of-package Supplemented Food caution identifier on a granola bar

Question 2. Back-of-package Supplemented Food Facts table on a granola bar



Question 3. Back-of-package cautionary labelling on a granola bar



Question 4. Front-of-package "High in" on a fruit juice cocktail

Question 5. Front-of-package Supplemented Food caution identifier on a caffeinated energy drink

Question 6. Back-of-package cautionary labelling on a caffeinated energy drink