(Response Deadline Sept 24, 2021)

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Policy, Planning and International Affairs Directorate
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Re: Feedback on Proposed Regulations for Supplemented Foods (Canada Gazette, Part 1, Volume 155, Number 26: Regulations Amending the Food and Drug Regulations - Supplemented Foods)

Dear Sir or Madam:

Thank you for the opportunity to provide feedback on the proposed amendments to the Food and Drug Regulations (FDR) regarding supplemented foods (SF) and supplemental ingredients (SI).

The development of a framework for regulating supplemented food products is of public health significance, and therefore, the Middlesex London Health Unit (MLHU) has prioritized a response for this important subject. Nutrition is a modifiable risk factor for the prevention of chronic disease and plays a significant role in an individual's overall physical and mental health throughout their lifespan.

MLHU acknowledges Health Canada's efforts to apply a risk-based approach in developing the proposed regulatory amendments. We also recognize that a streamlined framework for regulating supplemented foods has advantages (e.g., logistically, operationally) - both for the federal government as the body responsible for market approval of such products, and for the food industry.

However, while the proposed regulations include some potential strengths in terms of reducing regulatory barriers, MLHU recommends that the proposed framework be very carefully considered given the lack of evidence in support of health benefits for Supplemented Food (SF) products and the growing evidence of health risks of certain SF products. Our concerns are described in the attached.

The Middlesex London Health Unit looks forward to continuing to work in partnership with federal regulators in addressing the health concerns associated with 'supplemented' food products. For more information or to discuss further, please do not hesitate to contact myself or Donna Kosmack, Program Manager, Chronic Disease Prevention and Tobacco Control at (519) 663-5317 ext. 2302.

Sincerely,

Comments on the Proposed Regulations for Supplemented Foods

While there are some advantages to the proposed regulatory framework, MLHU has the following **key** concerns as they pertain to protecting and promoting population health:

1. **The proposed regulatory framework may lead to an increase in the availability of supplemented food products in the food supply which in turn, may pose risks to the health of the public, particularly to vulnerable population groups.**
   - As noted in the regulatory proposal, the supplemental ingredients used to develop supplemented food products, can pose a risk to health if they are overconsumed by the general population or consumed by populations who may be more vulnerable to their health impacts (e.g., pregnant women, children, youth). For example:
     - The regulatory proposal discusses the research which indicates that male children and young adults 12 – 30 years of age represent the largest proportion of caffeinated energy drink users, and that these drinks may be more likely to affect children and adolescents than they do adults.
     - Health Canada has previously indicated that *"in some cases, one energy drink could have more caffeine than the safe daily intake for many children and teens"*.
     - The Expert Panel previously convened by Health Canada reported a number of concerns related to the health impacts of caffeinated energy drink consumption, and recommended a range of related measures to protect the health of consumers. This includes the panel recommendations that energy drinks be designated and named as "stimulant drug containing drinks", and that they require a label indicating that such products are not recommended for children and adolescents under the age of 18 years.
   - As outlined in the objectives of the regulatory proposal, the proposed framework *"provides flexibility to adapt to new evidence related to supplemented foods and supplemental ingredients, thus supporting innovation in the food industry*".
     - Compared to the current approach (i.e., Temporary Market Authorizations), the proposed amendments appear to reduce barriers for the food industry to gain market approval for supplemented food products, including the potential for accelerated approval timelines. As such, industry may be encouraged to develop a wider variety of supplemented food products than what is currently available in the market.
     - An increased and wider variety of supplemented food products on the market over the long-term has the potential to increase public consumption of supplemented food products, including an increase in 'mixing' of supplemental ingredients (i.e., from intake of various types of supplemented products). This, in turn, may lead to an increase in adverse health effects within the population and in vulnerable populations when the supplemental ingredients consumed are associated with potential health risks.
   - The 'supplemented' and 'supplemental' terminology used in the proposed regulatory framework and any related consumer-facing language (e.g., on product labels, in marketing and advertising) may create a '*health halo*' effect for supplemented food products. The terminology may be misleading and/or misinterpreted by consumers, given the potential for a perceived association with health products such as vitamin and mineral supplements. As such, consumers may be encouraged to consume more of these products (i.e., through a '*health halo*' effect) and

may be less likely to understand the risks associated with consuming certain supplemented food products.

2. **The availability and promotion of supplemented food products within the food supply does not align with Canada's Dietary Guidelines.**
   - Canada's Dietary Guidelines outline that processed or prepared foods and beverages that contribute to excess sodium, free sugars, or saturated fat, undermine healthy eating and should not be consumed regularly.
     - Supplemented foods are **prepackaged** foods containing one or more supplemental ingredients, many of which fall under the umbrella of processed or prepared foods/beverages.
     - Increased availability and consumption of supplemented food products may come at the expense of consumption of the foods and beverages promoted within Canada's Dietary Guidelines (i.e., vegetables, fruit, whole grains, protein foods and water).
     - Including the term 'supplemented' (e.g. in the supplemented food facts table, on the Supplemented Food Caution Identifier) on the label of supplemented foods, may lead consumers to overestimate the healthfulness of those foods (i.e., the '*health halo effect*'). This is of particular concern given the fact that many of the foods in the List of Permitted Supplemented Food Categories are foods that Canada's Dietary Guidelines indicate should not be consumed regularly (e.g., sugary drinks such as soft drinks, juice, sports and energy drinks, and confectioneries such as candies, candy bars and chocolate).
   - Canada's Dietary Guidelines include consideration of the environmental implications of food choices and eating patterns; including the way that food is produced, processed, distributed, and consumed.
     - Supplemented food products are prepackaged products which may have negative environmental impacts given that they are highly processed and require packaging (e.g., wrappers, bottles) which may be harmful to the environment.

3. **The proposed regulatory framework is not accompanied by a comprehensive strategy to mitigate the health risks that may be associated with the proposed regulatory changes.**
   - While a risk-based approach was considered in the regulatory proposal development process, a full range of policy and program measures appears to be needed (e.g., additional restrictions on marketing/promotion, restrictions at point-of-purchase) to mitigate the health risks that may be associated with an increased availability of supplemented food products on the market over the long-term.
   - This is of particular concern for vulnerable populations (e.g., children and youth) who may be more susceptible to negative health effects from consumption of supplemented food products.
     - This includes youth aged 14-17 who are part of the age range (12 to 30 years of age) representing the largest proportion of caffeinated energy drink users, but for whom there may be fewer conditions and restrictions for industry to adhere to. For example, a cautionary statement indicating that those aged 14-17 "should not consume" such products, is not required on the label. As outlined in the regulatory proposal, the current approach places the onus on consumers aged 14 and above to interpret the

label and *"understand their caffeine consumption and manage within their recommended limits".*

Given the above key concerns, **Middlesex London Health Unit recommends the following**, for your consideration:

1. **Restrict use of the terms 'supplemented' and 'supplemental' in consumer-facing language (e.g., on product labels, through marketing and advertising).** This recommendation aligns with a risk-based approach to regulating supplemented food products in a manner that protects the health of consumers, including vulnerable populations. For example:
    - **Revise the language for the proposed Supplemented Food Caution Identifier (SFCI) symbol.** More specifically, replace the term 'supplemented' with language that conveys caution (e.g., 'warning') and makes specific reference to the cautionary statements on the other portion of the label for more information. The term 'supplemented' (along with an exclamation mark) may be not be interpreted by consumers as cautionary in nature and may not sufficiently warn consumers of the health risks associated with consuming the product. The SCFI symbol should use clear consumer-friendly language (e.g., "warning", "caution") to indicate risk and direct them to the cautionary statements on the other portion of the label to read more.

2. **Develop a communication campaign and related products to educate the public regarding the regulatory changes, including messaging pertaining to:**
    - a consumer-friendly overview of the regulatory changes.
    - how 'supplemented foods' and 'supplemental ingredients' are defined, with examples of such products.
    - the potential health risks associated with overconsumption of supplemented food products by the general population and of consumption among vulnerable populations, with specific examples (e.g., the risks of consumption of caffeinated energy drinks among children and youth).
    - how to identify supplemented food products in the market and interpret any applicable cautionary statements and warnings (e.g., how to look for and interpret the supplemented food caution identifier on the label).
    - the importance for Canadians to limit their consumption of processed/prepared food products, including supplemented food products, as per Canada's Food Guide and Canada's Dietary Guidelines.
    - that while supplemented foods may be promoted by the food industry as having physiological or health effects, individuals need not consume them in order to meet their dietary/nutritional requirements (i.e., but rather to follow the recommendations outlined in Canada's Food Guide).
    - the process for the public to report on adverse health effects or events due to the consumption of a supplemented food product, with strong consideration for inclusion of this information on the label of supplemented food products.

3. **Develop an evidence-informed, comprehensive strategy that establishes a range of policy and program measures to mitigate the possible negative health and environmental impacts of the proposed regulations, including consideration of:**
    - Limits on the number and variety of supplemented food products a company may develop within a specific time frame to mitigate potential increased availability of supplemented foods.
    - Restrictions on the types of products that can be formulated and available on the market to ensure that vulnerable groups (e.g., children and youth) are not targeted directly or indirectly through the product development and formulation phases. For example:
        - Restrictions on the use of 'kid/youth-friendly' flavours (e.g., 'cotton candy').
        - Restrictions on adding supplemental ingredients to products that are consumed more regularly by vulnerable populations such as children and youth (e.g., candies, certain beverages such as juice).
    - Conditions and restrictions on supplemented foods (e.g., 'do not consume' cautionary statements) for youth 14 – 17 years of age for products that may pose risk to their health (e.g., caffeinated energy drinks); similar to the considerations made to develop the conditions and restrictions required for children and youth under 14 years of age and also in consideration of the previously noted Expert Panel recommendations pertaining to caffeinated energy drinks.
    - Restrictions on marketing and promotion of supplemented foods that directly or indirectly target vulnerable populations such as children and youth up to 18 years of age. For example:
        - Restrictions related to sampling of products at any location where vulnerable populations (e.g., children and youth under 18 years of age) congregate, and/or locations where certain activities such as the provision of alcohol or engagement in high-intensity activities could further increase health risks when combined with the consumption of supplemented food products (e.g., caffeinated energy drinks).
        - Restrictions pertaining to branding, events and/or sponsorship.
    - Restrictions on sales at the point-of-purchase when there is the potential to mitigate health risks for vulnerable populations (e.g., prohibitions on sales of caffeinated energy drinks to children and youth under 18 years or age, restrictions related to product placement/location in stores and on shelves).

4. **Establish a transparent and comprehensive process to regularly gather and synthesize data and research evidence on the health risks associated with consuming supplemental ingredients and supplemented food products. Use such findings to inform, review and market approvals of supplemented food products and any ongoing amendments to the supplemented food regulations in the FDR.**
    - A comprehensive process to regularly review and synthesize data (including incident report data) and research evidence should be in place to inform product review/approvals and ongoing regulatory amendments in order to protect the health and safety of consumers. Findings from this process should be communicated to health officials and the public on an ongoing basis.
        - While recognizing that industry-driven data/evidence is relevant and informative, this process must also integrate data/evidence from unbiased, non-industry sources. This includes data and research that is neither collected/conducted, nor funded, by the food industry. Using unbiased forms of data/evidence in addition to incident report data to

inform approvals and regulatory amendments is required to protect the health and safety of consumers.

- A transparent and thorough process for reporting and investigating adverse incidents (i.e., adverse health effects) associated with the consumption of supplemented food products should be put in place. This process should be adequately communicated to the public and be integrated into the regulatory framework, where applicable (e.g., requirements for product labels to include adverse event reporting information).