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September 24, 2021

Re: Regulating Supplemented Foods & Natural Health Products, particularly, the mainstreaming of energy drinks, the fortification of junk food, and the under-regulation of natural health products

I am writing on behalf of the Centre for Health Science and Law (CHSL) to express concern about the 188-page proposal entitled “*Regulations Amending the Food and Drug Regulations (Supplemented Foods)*” and “*Amending the Natural Health Product Regulations.*”¹

1. Summary of the harm posed by Supplemented Food and Natural Health Products

The Supplemented Food proposal appears chiefly to be a vehicle for mainstreaming the advertising and sale of energy drinks that have, for several years, been the subject of persistent concerns about severe and sometimes fatal adverse health reactions in Canada, the United States, and Europe—possibly dangerous only to a small vulnerable population, such as those suffering from Long QT Syndrome. Energy drinks have been marketed as Natural Health Products, then as foods under temporary marketing authorizations because they contain substances that are generally not permitted to be added to foods. The Supplemented Food proposal also appears to revive a decade-old, rejected proposal to liberalize the discretionary fortification and marketing of, as a former minister of health opined, “junk food.” The Natural Health Product (NHP) labelling proposal appears to address only 3% of adverse reactions that are associate with labelling and is silent on numerous risk-related problems with the contents of the NHP packages flagged earlier in 2021 by the Auditor General of Canada.

2. Scope and nature of the Supplemented Foods category

According to the proposal, 79% of current “supplemented foods” product lines (SKUs) are manufactured by medium and large companies. If the sales volumes of the average medium and large companies were only five times larger than small companies, medium and large companies would command a 95% market share of supplemented foods which is indicative of the origin of

¹ *Canada Gazette Part I*, Vol. 155, No. 26, June 6, 2021 at pages 3,254-3,387 and 3,388-3,448. Available at: f

commercial pressure to implement these regulations. But, to be clear, the 611 products that Health Canada states are currently being marketed as “Supplemented Foods” represent approximately ½ of 1% of food product lines currently on in the Canadian marketplace; so, if the conversion of these products were delayed until a genuinely transparent consultation were held or until more forthcoming risk-warnings are mandated, more than 99% of the food supply would be completely unaffected.

Furthermore, like the decade-old, rejected proposal for foods to be fortified with vitamins and minerals at the discretion of food companies, Health Canada only definitively proposes to prohibit the following foods from being fortified/supplemented (at pages 3,302-3,303):

- foods specially formulated for infants (mainly breast-milk substitutes) or pregnant or breastfeeding women;
- foods formulated for special dietary purposes (e.g., meal replacements),
- alcoholic beverages;
- foods that are fortified for public health purposes (presumably on a mandatory basis, such as milk fortified with vitamin A); and
- unprocessed foods like fresh meat, fruits, and vegetables, though presumably any processing by a manufacturer itself would qualify a food for fortification.

Health Canada proposes to create an administrative “List of Permitted Supplemental Ingredients,” and a “Directory of Supplemented Food Caution Identifiers Specifications,” none of which were announced in the regulatory proposal even in draft form. There is not even an indication of whether these might comprise a few dozen or a few hundred substances, but one might infer that the list and directory would codify most or all permitted products currently permitted by Temporary Authorization Letters. Presumably, cautions for energy drinks would be sparse and inconsistent with adverse reaction reports and studies published in peer-reviewed scientific journals.

Nor does the proposal indicate what method of approval or toxicological testing would be required for supplemented food ingredients. However, section B.29.031 of the proposed regulation does not oblige the applicant to conduct a systematic review of studies of ingredients that were published in peer-reviewed scientific journals or to describe their search strategy (at page 3,376). This signifies that, like Health Canada’s Pest Management Regulatory Agency’s recently discredited approach to evaluating pesticide safety, Health Canada’s Food Directorate intends to rely chiefly on information provided by the commercial applicants. The PMRA’s approach may soon change.¹

Finally, the proposed “Supplemented Food Facts table (SFFt)” titled “!Supplemented Food” and even the “!Supplemented Food Caution Identifiers” appear as likely to be construed as an enthusiastic promotional claim as a risk warning. The label may also tend to imply that most of the pertinent information concerns nutrition. The proposal does not explain the rationale or evidence to justify positioning the exclamation point at the beginning of the titles, contrary to English and French grammar conventions.

3. Risks of Energy Drinks

CHSL reported an analysis of documented cases of seizure, cardiac arrest, and death attributed energy drinks to the Canadian Vigilance Program and the Auditor General of Canada on April 25, 2021.² Health Canada conceded that 377 of 611 Supplement Foods were energy drinks. In the same issue of the *Canada Gazette* Health Canada estimated (at page 3,398) that as few as 1%-2% of adverse reactions to Natural Health Products—the former regulatory category for energy drinks—are actually reported to its Adverse Reaction Database.

The second largest sub-category of Supplemented Foods—337 of 611—is “beverages, beverage mixes and concentrates.” This seems to indicate a willingness by the Food Directorate to approve the fortification/supplementation of products that former Conservative Minister of Health Leona Aglukkaq refused to allow for fear of being characterized as the “junk food queen.”³ Water and milk and the only beverages promoted in *Canada’s Food Guide*.

CHSL summarized reports of serious adverse health effects of energy drinks in its April 2021 [submission concerning the future of Health Canada Adverse Reaction Database](#); the harm is speculated to be caused by the addition of supplementary ingredients that are not generally permitted to be added to foods because their safety has not been evaluated. Health Canada’s Supplement Foods proposal indicates only that it proposes to prohibit the caffeination of products marketed specially for pregnant or nursing women and to mandate warnings on Supplement Foods with added caffeine to discourage mixing with alcohol and consumption by children under age 14. If such warnings were heeded by consumers, only a small fraction of serious adverse affects would be prevented.

The failure to address the safety of energy drinks is no trifling matter. The Regulatory Impact Assessment also misleads readers in not clarifying that energy drinks comprise 62% of Supplemented Foods currently on the market in Canada. The term energy drink (or its abbreviation, CED) is mentions only in passing in six paragraphs of the 128-page regulatory proposal and impact assessment that changes their regulatory status. Furthermore, 93% (99 of 107) of foods for which marketing authorizations were revoked or cancelled for noncompliance were energy drinks according to a [List of Foods that have Received Temporary Marketing Authorization Letters](#). There was no discussion of the reasons for these revocations in the proposal, let alone any means of addressing the risks.

Health Canada proposes that Supplemented Foods posing risks to consumers would be required to carry a “Supplemented food caution identifier (SFCI).” But officials have always failed mandate the disclosure of rare, but serious hazards caused by energy drinks and fail to consider other approaches to mitigate risks in the 128-page proposal. This indicates a high risk-tolerance of Health Canada officials about which they should be forthcoming with Canadians.

The Regulation Impact Assessment does not acknowledge any of the reports of adverse reactions deposited with the Adverse Reaction Database, the Canadian Food Inspection Agency, the scientific literature, on the news media. Ironically, Health Canada raises the risk of death only as a theoretical possibility (at page 3,393), when, in fact it has been repeatedly reported in the Adverse Reaction Database and the peer-reviewed literature for energy drinks. Since reports to the Adverse Reaction Database have been forwarded to the Canadian Food Inspection Agency, they are no longer pro-actively published, thereby depriving even the most conscientious consumers of the opportunity to conduct their own risk assessments.

4. Unaddressed Risks of Natural Health Products

A proposal to amend labelling requirements for Natural Health Products that was published in the same issue of the *Canada Gazette* purports to revamp labelling rules but concedes that only 3% of more than 10,000 adverse reaction reports per year (207 adverse reactions over two years only 1%-2% of which are reported) were attributable to label confusion (page 3,397).⁴ Moreover, an April 2021 [Auditor General of Canada evaluation of the regulation of NHPs](#) also indicated that the real problem is with what is inside the package, not what is on the label. The Auditor General concluded, in part: “Health Canada did not ensure that natural health products offered to Canadians were safe, effective, and accurately represented on the basis of appropriate evidence.”

5. Lack of transparency in Consultations

Although [consultations on the proposal for Supplemented Foods were described in the regulatory proposal \(at page 3269\)](#), there is [no notification of any such consultations among the 875 \(from December 2014 to today\) consultations logged in Health Canada’s Consultation and Stakeholder Information Management System \(CSIMS\)](#) which strongly indicates that this consultation was non-transparent and that Health Canada cherry-picked stakeholders to minimize adverse comment. In consultations on similar so-called “discretionary fortification” of foods more than a decade ago, there was a sharp difference of opinion between health organizations that unanimously opposed fortification of foods without a public health rationale, and food companies and industry associations that wanted more flexibility to fortify foods to make marketing claims regardless of public health justification. Health Canada also [failed to be transparent about a consultation on a controversial pesticide’s re-approval, glyphosate, as evidenced by CSIM records \(at pages 324 and 461-462\)](#). The Regulatory Impact Assessment reported no comments from health groups.

6. Concluding remarks about energy drinks, fortifying junk food, and regulating Natural Health Products

CHSL urges the new Minister of Health to direct officials to commission a systematic review of the published literature related to the health risks of energy drinks, and submit this for publication in the *Canadian Medical Association Journal* and nominate the members of the disbanded Ministerial Energy Drink Expert Advisory Group⁵ as potential peer-reviewers and reconcile the numerous adverse reaction reports and peer-review evidence reports of risks of energy drinks with the manufacturers’ claims of safety. Likewise, the damning report of the Auditor General and the aversion of former Minister of Health Leona Aglukkaq to being remembered as the “Junk Food Queen” should be sobering for anyone seeking to promulgate the Supplementary Food regulations.

Respectfully submitted,



Bill Jeffery, BA, LLB,
Executive Director and General Counsel

Endnotes

¹ The Federal Government's 2021 election platform committed to

“Strengthen the Pest Control Products Act to better protect our health, wildlife, and the environment. Align with world-leading approaches to transparency when reassessing pesticides already on the market and increase opportunities for independent scientists to have input into the decision-making process [related to pesticides and]... Invest in further government and independent science, including on water and soil monitoring and on the cumulative effects of multiple pesticides on health and the environment.”

Available at: <https://liberal.ca/wp-content/uploads/sites/292/2021/09/Platform-Forward-For-Everyone.pdf> at pages 51 and 79.

² CHSL. Comment on “Reporting Adverse Reactions to Marketed Health Products”: The case of energy drinks. Submission to Health Canada. April 25, 2021. Available at: http://healthscienceandlaw.ca/wp-content/uploads/2021/08/CHSL-Comments.AdverseReactions.NHPs_EnergyDrinks.pdf

³ Cathy Gulli. Junk food that's good for you? Manufacturers may gain the power to fortify products with nutrients. Maclean's Magazine. May 15, 2009. Available at: <https://www.macleans.ca/society/health/junk-food-thats-good-for-you/> ; and see: Eric Beauchesne and Wayne Kondro. Health Canada contemplates providing food industry with “discretionary” authority to fortify junk foods. *Canadian Medical Association Journal*. June 9, 2009. Available at: <https://www.cmaj.ca/content/cmaj/180/12/1196.full.pdf>

⁴ Although Health Canada described a series of consultations being held between 2016 and 2018 at pages 2,411-3,412, Health Canada's Consultation and Stakeholder Information Management System reveal only one such consultation since 2014: the present Canada Gazette proposal. Another tangentially related consultation conducted in late-2018 to early 2019 gathering input on a recall guide for drugs and NHPs. This appears to indicate another practice of cherry-picking consulted parties in Health Canada. The regulatory proposal described no criticisms or feedback of any kind from health or medical groups and did not mention the Auditor General's report published more than two months before the regulatory proposal was published in the *Canada Gazette*.

⁵ Dr. Robert Hamilton, Division of Cardiology, Hospital for Sick Children, Toronto; Dr. Noni MacDonald, Professor of Pediatrics, Dalhousie University; Ms. Patricia Malloy, Hospital for Sick Children, Toronto; Ms. Yola Moride, Associate Professor, Faculty of Pharmacy, University of Montreal, Dr. Jane Shearer, Faculty of Kinesiology, University of Calgary. Biographies are available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/activities/expert-panel-caffeinated-energy-drinks/biographies.html>