



CANADIAN HEALTH FOOD ASSOCIATION

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Submitted via e-mail to: supplementedfoods-alimentssupplementes@hc-sc.gc.ca

Supplemented Foods Team
Bureau of Nutritional Sciences
Food Directorate
Health Canada

To the Supplemented Foods Team:

Re: Feedback on the Consultation for the Compliance of Supplemental Ingredients Declared on the Labels of Supplemented Foods

On behalf of the Canadian Health Food Association (“CHFA”), we are writing to submit the following comments on the Consultation for the *Compliance of Supplemental Ingredients Declared on the Labels of Supplemented Foods* (“**Consultation Document**”).

As Canada’s largest trade association dedicated to natural health and organic products, CHFA is committed to representing our members and the industry on proposed regulatory changes that will directly influence their business operations. Our membership base consists of hundreds of businesses across Canada, including manufacturers, retailers, wholesalers, distributors and importers of natural health and organic products. These businesses produce and sell a variety of products including foods, vitamin and mineral supplements, herbal products, sports nutrition products, health and beauty aids, as well as products that fall within the definition of a supplemented food and would be subject to the proposed supplemental ingredient compliance requirements under the supplemented foods regulatory framework.

CHFA members have been manufacturing, packaging, labelling, importing and distributing what are now defined as supplemented foods since their inception, when these products were regulated as natural health products. Notably, CHFA members helped create quality guidance for natural health products when many supplemented foods were regulated under that framework. When these products transitioned to foods under the Temporary Marketing Authorization (“TMA”) process, CHFA members obtained Temporary Marketing Authorization Letters (“TMAL”) and supplied annual sales data, research as well as consumption incident reports to support the development of the supplemented food regulatory framework. During the transition from natural health product to a food sold under a TMA, the authorization process was completely administrative, there were no changes to manufacturing, including changes to tolerance limits and overages. Accordingly, the approach

When we all do well, Canadians live well.

proposed by Health Canada and the Canadian Food Inspection Agency (“CFIA”) regarding the compliance limits for supplemental ingredients represents a significant departure from previous processes and will have a significant impact on CHFA members, especially as it relates to costs.

Compliance of supplemental ingredients is fundamental to the ability of the retail supply chain to implement proper processes to provide certainty to businesses operating in the Canadian marketplace – from manufacturers, to distributors and importers, and retailers. The implementation of the proposed Consultation Document would require certain manufacturers of supplemented foods to change the formulation and/or the shelf life of their supplemented food products, or incur unnecessary legal risks, including potentially class action litigation. At minimum, Health Canada quantified the cost to industry of product reformulations to be approximately \$19.4 million or \$15.8 million present value over a 10-year time period.¹ Implementing a compliance test that increases costs to industry is a departure from Health Canada’s position that most supplemented food products would not be reformulated and is contrary to the cost benefit analysis required to substantiate the new regulations.

I. CHFA General Comments on the Consultation Document

We understand based on our review of the Consultation Document that the compliance limits for supplemental ingredients are categorized by two types:

1. **Supplemental ingredients that have minimum compliance limits** (including, vitamins, mineral nutrients and amino acids as supplemental ingredients found in Parts I – III of the *List of Supplemental Ingredients*)
2. **Supplemental ingredients that have maximum compliance limits** (including caffeine and taurine, essentially the ‘other supplemental ingredients’ found in Part IV of the *List of Permitted Supplemental Ingredients*)

Our main area of concern with respect to the proposed compliance limits is the lack of tolerance limits and overages for the supplemental ingredients found in Part IV of the *List of Permitted Supplemental Ingredients*, which currently consists of caffeine and taurine, but in the future may include other ingredients. Based on our review of the Consultation Document, the prescribed limit for these supplemental ingredients is restrictive as it does not permit any

¹ Canada Gazette, Part I, Volume 155, Number 26: Regulations Amending the Food and Drug Regulations (Supplemented Foods). Regulatory Impact Analysis Statement < <https://www.gazette.gc.ca/rp-pr/p1/2021/2021-06-26/html/reg3-eng.html>> (Accessed September 22, 2022).

upper tolerance limits or overages. In our view, it is unreasonable to provide no upper tolerance limits or overages for these supplemental ingredients as this flawed approach:

- a) **Does not take into consideration standard Good Manufacturing Practices (“GMPs”)** - Specifically the lack of tolerance limits in the proposed approach does not take into account the measurement uncertainties that can occur as part of systemic and random errors that are present, as part of the manufacturing process and finished product testing. Additionally, it does not account for compositional variations of supplemental ingredients which are outside the manufacturer’s control.
- b) **Is not supported by a strong scientific or safety rationale** - From our review of the Consultation Document, we note that Health Canada has not provided a sound rationale as to why a reasonable upper tolerance or overage has not been considered.
- c) **Is not consistent with the purpose of the overage, as described by Health Canada**, which is intended to be the minimum amount of ingredient that must be added to assure that the quantity declared on the label is met throughout a product’s shelf life. Manufacturers are deprived from the opportunity of ensuring that the average label quantity is maintained within the accepted range throughout the shelf life of a supplemented food containing caffeine and taurine. This is inconsistent with the common practice to allot for overages during formulation to maintain quality. Given the restrictive tolerance limits, the lack of prescribed overages may also further contribute to the inconsistencies between the actual amount of supplemental ingredients added to the supplemented foods and the amounts declared in the Supplemented Food Facts table (“SFFt”) for these supplemental ingredients. Manufacturers may be required to reformulate their existing products and/or shorten their shelf life, both of which will unnecessarily increase costs and food waste.
- d) **Is not consistent with Health Canada’s published health risk assessment on caffeinated energy drinks² with respect to the lack of tolerance limits and overages for caffeine and taurine.** Specifically, Health Canada’s health risk assessment incorporated overages in the evaluation of caffeine and taurine as supplemental ingredients. The study methodology states that the risk analysis was

² Sébastien La Vieille, Zoe Gillespie, Yvette Bonvalot, Karima Benkhedda, Nancy Grinberg, Joel Rotstein, Jennifer Barber, and Andrew D. Krahn. Caffeinated energy drinks in the Canadian context: health risk assessment with a focus on cardiovascular effects. *Applied Physiology, Nutrition, and Metabolism*. 46(9): 1019-1028. <https://doi.org/10.1139/apnm-2021-0245>

conducted on products that were in the marketplace at the time. Accordingly, since products that were in the marketplace were manufactured under standard conditions, specifically under GMPs, this confirms that the products included in the study were manufactured with current tolerance limits and overages at the time.

a. Legal Risks Imposed by Proposed Compliance Requirements

The Consultation Document introduces legal risks for manufacturers, distributors and advertisers of supplemented foods – specifically as a result of the proposed compliance limits for supplemental ingredients that have maximum compliance limits. Maintaining label claims within a reasonable range is vital to ensuring that consumers are not misled as to the amount of supplemented ingredients provided in a supplemented food. Manufacturers are prohibited from labelling foods in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding the **quantity or composition of foods**. The proposed criteria with respect to the supplemental ingredients does not permit manufacturers to reasonably maintain the declared value of ingredients listed in Part IV of the *List of Permitted Supplemental Ingredients*, mainly taurine and caffeine. This restriction is introducing a legal risk to manufacturers without an equivalent safety and scientific substantiation demonstrating the impact or public health benefit of the proposed restrictions. Alternatively, modifying the shelf life of supplemented food products to account for these restrictions would be costly and unreasonable as many supplemented foods have a short shelf life of 18-24 months. Consequently, the proposed compliance restrictions renders accurate and non-misleading declared values of certain supplemental ingredients untenable.

b. Consultation Timeline

We note that Health Canada originally provided only seventeen (17) days to comment on this significant complex proposal. We understand that stakeholders were provided with extension of twenty-three (23) days to provide comments, and kindly agreed to a further extension of five (5) days; however, given that the majority of the consultation period was during the summer months, it was not sufficient time to collect comprehensive feedback from global suppliers that would be greatly impacted by the proposal. Given this limitation, we request that Health Canada and CFIA engage in further consultation with CHFA and other stakeholders prior to finalizing the draft compliance limits for supplemental ingredients.

c. General recommendations:

Generally, we recommend that tolerance limits for the quantity of supplemental ingredients found in Part IV of the *List of Permitted Supplemental Ingredients*, should conform to the relevant and comparable GMP and scientific standard. The overages, in our view, should be consistent with GMP or alternatively within the range of the maximum amounts assessed by Health Canada in the health risk assessment. We note that these amounts exceed the maximum amounts per serving of stated size as per the *List of permitted supplemental ingredients* and by Health Canada own determinations does not pose a health risk. We have outlined the sections below our detailed concerns and recommendations with respect to the proposed Consultation Document.

II. Supplemental ingredients that have maximum compliance limits

The Consultation Document states that the overages of certain supplemental ingredients must be within GMP and not pose a safety concern. Health Canada has taken the position, based on a risk assessment that an overage that falls within 150% of the declared value for the mean and composite sub-samples has been determined to be safe for supplemental ingredients that have minimum compliance limits. We understand, based on our review of the Consultation Document that the overages of some supplemental ingredients (e.g. potassium) are assessed on a case by case basis and in some cases, overage above 150% of the declared value may be investigated further to determine if there is a risk to health. In our view, Health Canada has already performed a risk assessment to determine that caffeine and taurine levels at or below 400 ppm (180 mg) and 2000 mg respectively in caffeinated energy drinks do not pose a risk to health.

These criteria on the application of overages for supplemental ingredients that have minimum compliance limits can also be applied to caffeine and taurine. This would mean allowing caffeine and taurine to have overages that are within GMP or alternatively, supply a reasonable overage limit, provided the amounts of the ingredients do not exceed the maximum amounts determined by the health risk assessment that was conducted by Health Canada. This will ensure that the declared label quantity is accurate and not misleading and will allow the declared quantities to be maintained within an acceptable range throughout the shelf life of a product without presenting a health risk. This is consistent with Health Canada's Guidance on Supplemented Foods Regulations, which states that:

The overage for an SI should be based on the minimum amount of the ingredient that must be added to assure that the quantity declared on the label is met, within acceptable tolerances, throughout a product's shelf life. A number of variables affect the amount of overage that is needed for a specific SI, including the food matrix, method of manufacture, type of packaging, storage conditions, and shelf life. A food stability study can help the manufacturer determine the minimum amount of the SI to add during manufacturing in order to meet the quantity declared on the label at the end of the shelf life and avoid excessive overages. Manufacturers must be able to justify the overage amount, as well as ensure that the ingredient content meets the quantity declared on the label, is not likely to result in an excessive overage, and will not present a risk to the health of consumers.³

Health Canada's health risk assessment on caffeinated energy drinks determined that caffeine and taurine can be safely consumed at 400 mg/day and 3g/day respectively. Therefore, the rationale for overages and tolerance limit for caffeine and taurine specifically is substantiated by safety and scientific evidence.

III. Supplemental ingredients that have minimum compliance limits

We requested feedback regarding the concerns with respect to supplemental ingredients that have a minimum compliance limit. Due to the limited time provided to obtain feedback from CHFA members on the Consultation Document, we reserve the right to provide additional feedback.

IV. Tolerances for Supplemental Ingredients (Criterion 2)

In our opinion, the current acceptance criterion 2 for supplemental ingredients such as caffeine and taurine does not account for variances in the composite sub-samples. Since each criterion has to be met, it is unreasonable that each composite sub-samples can be up to 1.5 times more than the declared supplemental ingredient value, but the mean value of the composite sub-samples is restricted to the declared amount (pre-rounding). Based on sound science and GMP principles, it would be reasonable to apply an upper tolerance for these ingredients (e.g. 10% as per the comparable USP Monograph) to the mean value to accommodate the potential variance in the various composite sub-samples. It is unreasonable to offer no tolerances as it relates to the mean given that this value is derived from the composite sub-samples. Furthermore, this acceptance criteria does not take into account measurement uncertainty as it relates to manufacturing or analytical testing. Measurement interference is often unavoidable, it is unreasonable to ignore these variabilities as accounting

³ Health Canada. Guidance Document: Supplemented Food Regulations (July 2022).

for them is in fact part of good manufacturing practice operating standards.

Even the *United States Pharmacopeia (USP)*, a global leader in testing standards, recognizes that tolerances are required as part of GMP operating standards and finished product testing. This is demonstrated in the USP Caffeine Citrate Oral Solution Monograph (“**USP Monograph**”) which provides an upper tolerance limit of 10%. This USP Monograph is particularly relevant to the discussion of caffeinated energy drinks, which are arguably caffeine oral solutions.

The restrictive tolerances essentially force manufacturers to significantly inflate the declared supplemental ingredients, essentially creating an upper tolerance. This is demonstrated by Health Canada’s own example on page 29 of the Consultation Document. In the example, the declared value of caffeine is 100 mg. However, the laboratory results indicate that the composite sub-samples contain 85.8 mg, 88.1 mg and 82.4 mg of caffeine (mean = 85.4 mg). Based on the review of the sub-samples, the amount of caffeine presumably added in the manufacturing processes is almost 15% less than the declared value of caffeine. If the manufacturer intended to add 100 mg of caffeine, then we would expect to observe values such as 95 mg or 102 mg in the composite sub samples for example, not simply a scattering of values approximately 15% less than the declared value. In our view, this is consistent with our hypothesis, as it would appear that the declared value was inflated by 15% even by way of example, in order to meet the strict compliance criteria. Tolerance limits are intended to recognize the variability inherent in ingredient concentrations and to encourage manufacturers to label the food with the true lot average. These restrictions do not allow for the variability that is inherent in the manufacturing process.

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Example 3

Caffeine

Declared amount: 100 mg

Lab results

- Composite sub-samples = 85.8 mg, 88.1 mg, 82.4 mg
- Mean = 85.4 mg
- Standard deviation (SD) = 2.87

$$99\% \text{ lower confidence limit} = [(0.4344 \times \text{SD}) \div \text{mean}] = [(0.4344 \times 2.87) \div 85.4$$

mg] = 0.0146

Maximum pre-round

- For caffeine as a supplemental ingredient: round to the nearest 1 mg
- Maximum pre-round: declared value of 100 mg + 0.4 mg = 100.4 mg

Compliance criteria

- Criterion 1 compliance limit: Each composite sub-sample must be $\leq 150\%$ of declared value
 - (maximum pre-round + 50% of declared value) = 100.4 mg + 50 mg = 150.4 mg
- Criterion 2 compliance limit: Mean must be less than or equal to the declared value
 - (maximum pre-round) = 100.4 mg
- Criterion 3 compliance limit: 99% lower confidence limit must be ≤ 0.1
- Deficiencies: each composite sub-sample and mean must be within GMP and not misleading
 - Deficiency for each composite sub-sample: 50% of declared value has been determined to be not misleading
 - 50% of declared value = (100 mg x 0.5) = 50 mg
 - Deficiency for the mean: 80% of declared value has been determined to be not misleading
 - 80% of declared value = (100 mg x 0.8) = 80 mg

Assessment of declared value

- Criterion 1: Compliant: each composite sub-sample ≤ 150.4 mg
- Criterion 2: Compliant: mean ≤ 100.4 mg
- Criterion 3: Compliant: 99% lower confidence limit ≤ 0.1

V. Supplemental Ingredient Rounding Rules

We requested feedback regarding the concerns with respect to supplemental ingredients rounding rules. Due to the limited time provided to obtain feedback from CHFA members on

the Consultation Document, we reserve the right to provide additional feedback.

VI. Conclusion

We would recommend that Health Canada prescribe a reasonable upper tolerance limit for supplemental ingredients found in Part IV of the *List of Permitted Supplemental Ingredients*, mainly caffeine and taurine – and consult on those limits prior to finalizing the guidance. We reiterate that Health Canada has not provided scientific basis nor safety rationale to substantiate the lack of tolerance limits or overages for these ingredients. In fact, these proposed compliance limits are inconsistent with scientific standards that recognize that upper tolerances are required as part of GMP to account for variability. Health Canada has established, through a comprehensive health risk assessment that there is a safe range with respect to caffeine and taurine that currently exceed the maximum amounts permitted in the *List of Permitted Supplemental Ingredients*. Further, these compliance limits are not compatible with Health Canada's position that products would not be reformulated after the implementation of the *Supplemented Food Regulations*.

The impact of these compliance limits is important to our industry as it would have a significant cost impact on manufacturers that are currently in the market. For these reasons, we strongly advise that Health Canada and the CFIA engage in further consultation with CHFA and other stakeholders in efforts to finalize compliance limits for supplemental ingredients.

Kind regards,

A handwritten signature in black ink, appearing to read 'Sonia Parmar', is written over a white background.

Sonia Parmar
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