Council for Responsible Nutrition
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May 25, 2024

USA WTO TBT Enquiry Point
Standards Coordination Office (SCO)
National Institute of Standards and Technology (NIST)
Email: usatbtep@nist.gov

Enforcement & Compliance Unit
Office of Trade Agreements Negotiations and Compliance (TANC)
Email: tanc@trade.gov]

Office of Consumer Goods
International Trade Administration
U.S. Department of Commerce

Office of the U.S. Trade Representative
Executive Office of the President

Foreign Agricultural Service
U.S. Department of Agriculture

Dear USA WTO TBT SCO and TANC,

Re: USMCA Non-Compliance Concerns Regarding Health Canada's Proposed Fees For Natural Health Products

The Council for Responsible Nutrition (CRN[1]) is a Washington, D.C.-based trade association representing 200 dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. As the leading trade association for the dietary supplement, functional food and nutritional products industry, CRN represents manufacturers of dietary ingredients and of national brand name and private label dietary supplements and functional foods, many of which are multinational and already actively selling ingredients, finished products and services globally. CRN membership is made up of many companies that sell into Canada, as well as Canadian companies selling into the U.S. and beyond.

CRN is submitting this letter on behalf of CRN Members to the USA WTO TBT Enquiry Point Standards Coordination Office (SCO) and the Office of Trade Agreements and Compliance (TANC) to raise concerns regarding Health Canada's proposed fees for natural health products (NHPs) and their inconsistency with the United States-Mexico-Canada Agreement (USMCA) and World Trade Organization (WTO) Agreements.

[1] The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 200 dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org. Follow us on Twitter @CRN_Supplements, Facebook, and LinkedIn.

To our knowledge, Canada has not published a WTO notice for the proposed fees. However, Health Canada under the Natural and Non-prescription Health Products Directorate (NNHPD) is undertaking a consultation and seeking feedback on the proposed measure from NHP stakeholders. The consultation is set to close for new input on May 25, 2024 at 11:59 EST. The fees are currently proposed to be implemented in December 2025.

Health Canada regulates dietary supplements as NHPs in Canada. To be legally sold in Canada, all NHPs must have a product licence, and Canadian sites that import NHPs must have site licences. Currently, Health Canada does not charge fees for obtaining the requisite licences. However, Health Canada is now proposing to implement 3 categories of fees which it links to recovery of costs associated with specific services (i.e., regulatory activities) it conducts, as follows:

- "Pre-market Evaluation" fees to assess and license new products entering the Canadian market or to amend existing product licences,
- "Site License" fees to assess and license facilities that manufacture, import, label, or package health products, and
- "Right to Sell" fees to allow companies to sell their products in Canada for post-market surveillance and regulatory compliance and enforcement activities.

CRN has serious concerns regarding the proposed fees, their impact on market access for exports of goods regulated as NHPs in Canada from other USMCA parties, and the proposal's apparent non-compliance with Canada's commitments to national treatment and equity in conformity assessment fees under the USMCA. These concerns are summarized below.

Fee Proposal Contravenes National Treatment Obligations by Imposing a Inequitable Burden on Foreign Products and Indirect Protection to Domestic Production

- USMCA Article 11.3.1(c) incorporates by reference Article 5.2.5 of the WTO TBT Agreement. Article 5.2.5 of the WTO TBT Agreement requires that fees charged for the assessment of conformity of imported products be equitable to those charged for other like products (domestic or otherwise).
- USMCA Article 2.16.1 requires compliance with Article VIII:1 of the GATT 1994, which requires that all fees and charges of whatever character imposed in connection with importation (including those relating to licensing, documentation, analysis and inspection) not represent an indirect protection to domestic products.

Contrary to these obligations, Health Canada's proposal regarding site licencing fees advantages domestically-produced goods over imported goods. As currently proposed, NHP product licence holders that contract with foreign manufacturers and import NHPs into Canada are subjected to a greater regulatory and fee burden relative to NHP product licence holders that contract with Canadian manufacturers. This is due to the requirement for all foreign manufacturers, packagers and labelers to be added to an importer's Site Licence through amendments. Such licence and amendment fees would need to be absorbed by product license holders, and likely, costs would be trickled down to the US consumer. By contrast, were the product licence holder to contract with a domestic Canadian manufacturer, no site license or amendment fees would be incurred. Furthermore, Health Canada takes an inefficient approach to reviewing foreign sites in a manner that materially adds to the overall cost. For example, when an importer adds a US manufacturer, Health Canada reviews detailed information with respect to that manufacturer. When another importer subsequently adds the same manufacturer, Health Canada repeats that review. The fee structure contravenes Canada's obligation to ensure that importation fees do not indirectly protect domestic production, and treats foreign manufacturers inequitably contrary to trade obligations.

Impact on the United States

The currently proposed fees, if enacted, will impose an inequitable and unjustified financial burden on US product licence holders and discourage US manufacturing and/or importation of responsibly manufactured cross-border products that are value-added and sought by Canadian NHP users.

The adverse impact on US production is expected to represent a significant economic loss for the United States. Exports of packaged medicaments from the United States to Canada were valued at $3.73 Billion in 2021. Exports of other edible preparations to Canada were valued at $1.47 Billion.][2]

- If the fee structure is implemented as proposed, there will be an increase in the cost of products manufactured in the US and being exported to Canada. This will result in the loss of sales, and the ripple effect as jobs are lost in the US manufacturing sector for these products.

- It is unclear how products beings sold via e-commerce internet sites will be affected, but conceivably there will be a transition by the Canadian NHP users to seek lower cost products via that channel. These products may be of poorer quality, fake or knock-off products, and/or illegal products. A possible unintended consequence of this proposal is it may or will create for the regulated sector or for the market in general, and the increased reliance on a much-less regulated and often clandestine internet market.

[2] OEX, Packaged Medicaments in the United States; OEX, Other Edible Preparations in the United States

CRN and CRN Members respectfully request that the United States WTO TBT SCO and TANC Offices consider our comments in the spirit in which they are being offered, as we recommend that you urge Health Canada to reconsider its fee proposal in respect of natural health products to ensure that it is fair, equitable and proportionate to costs incurred, and otherwise compliant with Canada's international obligations.

Respectfully submitted,

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