AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

November 13, 2023

U.S. WTO TBT Inquiry Point
Standards Coordination Office
National Institute of Standards and Technology
Via email: usatbtep@nist.gov

Re: United States-Mexico-Canada Agreement Non-Compliance Concerns Regarding Health Canada's Proposed Fees for Natural Health Products (No WTO Notification)

Dear Colleagues,

The American Herbal Products Association (AHPA), as a trade association representing companies marketing natural health products (NHPs) in Canada, has concerns regarding Canada's proposed cost recovery fees for NHPs and their inconsistency with the United States-Mexico-Canada Agreement (USMCA) and World Trade Organization (WTO) Agreements.

AHPA is the leading trade association and voice of the herbal products industry. AHPA is comprised of U.S. domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters and distributors of herbs and herbal products. AHPA's members are engaged in the commerce of herbs and herbal products and numerous AHPA members located in the United States or in Canada sell NHPs in compliance with Canada's current regulations for such products. AHPA's members therefore have an interest in the subject of the recent Health Canada consultation regarding the introduction of a cost recovery fee system for NHPs.

Canada has undertaken a public consultation and is seeking feedback on the proposed measure from NHP stakeholders. The consultation closed to public input on August 10, 2023. Health Canada indicates that feedback received will be used to "refine" the proposal, after which the fee order will be published. The fees are currently proposed to be implemented on April 1, 2025. To our knowledge, however, Canada has not published a WTO notice for the proposed fees.

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

- "Pre-market Evaluation" fees accounting for 75% of total costs incurred to assess and license new products entering the Canadian market or to amend existing product licenses,

- "Site License" fees accounting for 100% of total costs incurred 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 and accounting for 67% of total costs for post-market surveillance and regulatory compliance and enforcement activities.

AHPA 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.

USMCA Articles 2.16 & 11.6: The Fee Proposal Contravenes the Requirement that Conformity Assessment and Import Fees be Limited to Cost Recovery

The regulatory activities Health Canada conducts in respect of NHPs and for which is proposes to charge the fees are "conformity assessment procedures" within the meaning of USMCA.

Article 11.6.9(a) of USMCA restricts all fees imposed in respect of conformity assessment services to the cost of services rendered. Further, Article 11.6.9(b) USMCA requires that fees only be charged with respect to conformity assessment services if they are imposed to recover costs of services rendered (and not for any other purpose).

USMCA Article 2.16.1 requires compliance with Article VIII:1 of the General Agreement on Tariffs and Trade (GATT 1994), Article VIII.1 of GATT 1994 requires that all fees and charges of whatever character imposed in connection with importation be limited in amount to the approximate cost of services rendered. Several of the proposed fees, including site licensing fees for importers and the "right to sell fee," are charged in connection with importation.

Health Canada's fee proposal does not comply with these obligations. Health Canada characterizes each of the newly proposed fees as a form of "cost recovery". However, the fees are not limited to recovering costs incurred for services rendered to applicants. Rather, they include "prospective costs" of hypothetical improvements to the NHP program that will not have been implemented at the time the fees are charged. Using the proposed fees as a revenue gathering tool to cover costs of systemic improvements is non-compliant.

Even with respect to Health Canada's current costs, it appears that the proposed fees will far exceed Health Canada's actual costs. As one example, site license amendment fees charged to importers regarding the addition of foreign sites are duplicative and disproportionate, in that each time a foreign manufacturer is added to a different importer's Site License, that amendment has a fee associated with it, even if the foreign manufacturer is the same. This structure unreasonably and unnecessarily penalizes importers of U.S. manufactured goods by artificially duplicating charges for regulatory costs that Health Canada would not incur multiple times, and is not justified as a cost recovery measure.

Fee Proposal Contravenes National Treatment Obligations by Imposing an 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.

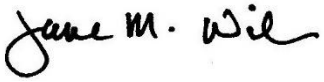
Contrary to these obligations, Health Canada's proposal regarding site licensing fees advantages domestically produced goods over imported goods. As currently proposed, NHP product license holders that contract with foreign manufacturers and import NHPs into Canada are subjected to a greater regulatory and fee burden relative to NHP product license holders that contract with Canadian manufacturers, due to the requirement for all foreign manufacturers, packagers and labelers to be added to an importer's Site License through amendments. Such license and amendment fees would need to be absorbed by product license holders. By contrast, were the product license holder to contract with a domestic manufacturer, no site license or amendment fees would be incurred. 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.

The currently proposed fees, if enacted, will impose an inequitable and unjustified financial burden on U.S. product license holders and discourage U.S. manufacturing of products for the Canadian market.

AHPA requests that the United States urge Health Canada to reconsider its fee proposal with respect to natural health products to ensure that it is fair, equitable and proportionate to costs incurred, and is otherwise compliant with Canada's international obligations.

We appreciate your assistance and look forward to your response.

Respectfully submitted,



Michael McGuffin
President
American Herbal Products Association
8630 Fenton St., Suite 123
Silver Spring, MD 20910
(301) 588-1171 x201
mmcguffin@ahpa.org

Jane Wilson
Director of Program Development
American Herbal Products Association
8630 Fenton St., Suite 123
Silver Spring, MD 20910
(301) 588-1171 x108
jwilson@ahpa.org