

February 10th, 2021

The Honourable Mary Ng, Minister of Small Business, Export Promotion and International Trade
The Honourable Patty Hajdu, Minister of Health

Dear Ministers,

Re: Request for Creation of New Export Certificate to Accommodate Export of Canadian Manufactured Cosmetics to China (Without Animal Testing)

1. Request

We are writing to you to request the establishment of a new Government issued or authorized GMP compliance certificate to facilitate the export of Canadian manufactured cosmetic products to the People's Republic of China. This will exempt such exports from animal testing requirements in China.

Although this request may sound straightforward, we understand from our work with Health Canada officials that it will likely require a novel approach, as well as direction from senior officials, to achieve.

We can confirm that in accommodating the new Chinese requirement for government issued or authorized compliance certificates, Canadian-based cosmetic manufacturers will be able to facilitate and potentially EXPAND exports to China. Time is, of course, of the essence given the ability of other jurisdictions to accommodate the new Chinese requirements for compliance certificates. Failure to act will place Canadian manufacturing at a disadvantage.

We are therefore requesting a virtual meeting with the appropriate officials from Health Canada, Global Affairs - International Trade, and Cosmetics Alliance to discuss how this matter can be addressed to create a timely opportunity for Canadian cosmetic manufacturers and avoid the loss of export sales.

2. Background

(a) China's Requirement for Animal Testing on Imported Cosmetics

Until recent regulatory reforms, the Chinese regulator (China's National Medicinal Products Administration or NMPA) did not treat domestic and imported "non-special" (e.g. non-therapeutic) cosmetic products equally. Imported cosmetics, for example, were required to undergo certain safety testing using animals which industry and most other regulatory authorities have abandoned due to the availability of non-animal alternatives.

Given the concern with animal testing in general – and certainly with the unnecessary cosmetic animal testing required for products imported into China - this made it difficult for international (including Canadian) manufacturers to continue to maintain and grow their businesses in China.

(b) China's New Cosmetic Regulation - Exemption to Animal Testing on Imports

The recent adoption of a new cosmetic regulation by China established an exemption to the animal testing requirements, on the condition that the importer can provide a GMP certificate (or equivalent)

issued by the exporting country's regulatory body substantiating that the product is recognized as being manufactured in accordance with a reasonable quality management standard [Article 11].

Compliance with these standards is not the issue for Canadian cosmetic manufacturers – they comply. The issue is that the certificate verifying compliance **MUST be issued by the “exporting country’s regulatory body”** – which for Canadian manufacturers is Health Canada. At the current time, Health Canada does not issue such certificates which is the similar situation in many jurisdictions including the United States and European Union. Such certificates of compliance are currently issued by trade associations, including Cosmetics Alliance.

Despite significant lobbying from industry from around the globe, China at this point will not accept certificates of compliance from non-government authorities.

(c) Impediments to Health Canada Issuing Compliance Certificates

Canada’s *Cosmetic Regulations*, as in most jurisdictions, is NOT based on pre-market licencing but on notification to the regulator and in-market controls. Cosmetics manufacturers must comply with regulations mandated under the *Food & Drugs Act* including filing a *Cosmetic Notification* with Health Canada if the product is to be sold in Canada. Health Canada does undertake in-market product inspections and manufacturing site audits from time to time, as well as overall post-market surveillance, but it does not specially licence cosmetic manufacturing sites.

Consequently, as Health Canada officials have advised us, the current Canadian regulatory regime does NOT allow for the issuing of such a quality management certificate for “cosmetics” as required by China.

(d) Industry Issued Export Certificates

As Health Canada is aware, Cosmetics Alliance has for many years offered an Export Certificates Program to exporters (both member and non-member companies). The program creates the legally binding certification documentation to verify compliance with Canadian regulations, standards, and practices (including GMPs). Our staff, who are familiar with product requirements, facilitate the necessary documentation provided by the importing jurisdiction. A legal liability for the exporter is created through sworn affidavits (for which swearing a false affidavit is an offence).

Regrettably, Cosmetics Alliance does not meet the Chinese requirement of being a government authorized body. A recent letter provided by Health Canada recognizing our service has not proved suitable to meet the Chinese requirement, thereby leaving Canadian-based manufactures without a means to avoid unnecessary animal testing.

(e) Recent Developments in France

Following the issue being raised by the French cosmetics industry and their national trade association FEBEA, it was recently announced by the French National Agency for the Safety of Medicines and Health Products (ANSM) that they will issue certificates to sites that manufacture “ordinary” cosmetic products. As of January 12th, the ANSM developed an online platform allowing cosmetic and personal care manufacturers to download the documents necessary to obtain the certificate, allowing all French cosmetics manufacturers to export to China without their products being tested upon arrival. This announcement recognizes the urgency of the situation and sets a precedent for action in Canada.

3. Considerations

As “cosmetics-like” products can include “natural health products” (NHP) and “non-prescription drugs” as defined by the *Food & Drugs Act*, many manufacturing sites have a “Site Licence” (SL) or “Drug Establishment License” (DEL) issued by Health Canada. As such, Health Canada already ensures that these sites meet the standards required and therefore may be able to issue a certificate acceptable to China.

However, for cosmetics manufactured in facilities that do not make NHPs or non-prescription drugs, these sites are not licensed by Health Canada nor specifically mandated to meet cosmetic GMPs. Although Cosmetics Alliance’s Export Certificate Program does ensure compliance with GMPs and other standards, we are not an authorized or government authority. Further discussions are required for which the developments in France may provide some innovative approaches.

4. Urgency – Protecting and Growing Canadian Manufacturing and Exports to China

Cosmetics Alliance members have advised that if a workable solution can be developed, it would create a significant opportunity for manufacturing cosmetics in Canada. This includes the shifting of production from other facilities to Canadian sites so that products can be exported to China without animal testing requirements. This is surely an opportunity that we must move quickly on, and for which we need the direction and cooperation of senior officials from both of your Ministries.

5. Contact Information

Diane Kozak of my office is available to arrange a virtual meeting with the appropriate officials from Health Canada and Global Affairs - International Trade. She can be reached at dkozak@cosmeticsalliance.ca or (905) 890-5161 Ext. 223. Should you have any questions or require more information, please contact me at dpraznik@cosmeticsalliance.ca or 647-298-1152.

We look forward to working with you on this issue which could bring great opportunities for manufacturing in Canada.

With best regards,



Darren Praznik
President & CEO, Cosmetics Alliance Canada

Cc:

Dr. Stephen Lucas, Deputy Minister of Health Canada

Ms. Isabella Chan, Assistant Deputy Minister, HECS

Mr. Pierre Sabourin, Assistant Deputy Minister, HPFB

Mr. Dennis Darby, President & CEO, Canadian Manufacturers & Exporters