COSMETICS ALLIANCE CANADA | The Voice of Canada's Personal Care Products Industry

L'ALLIANCE DE L'INDUSTRIE COSMÉTIQUE DU CANADA | La voix de l'industrie canadienne des produits de soins personnels

Issued June 29, 2021 (Finalized: August 6, 2021)

Proposal to Health Canada

for a

Voluntary Certification Program

to

Meet China's Regulatory Exemption

for

Animal Testing Requirements for Imported Cosmetics

Submitted by Cosmetics Alliance Canada

June 29, 2021 (Finalized: August 6, 2021)

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EXECUTIVE SUMMARY

In our letters dated February 10th and May 13th, 2021, Cosmetics Alliance Canada wrote to federal Ministers the Honourable Patti Hajdu (Health) and the Honourable Mary Ng (Small Business, Export Promotion, and International Trade) requesting the establishment of a Government issued "GMP certificate" to facilitate the export of Canadian manufactured cosmetic products to the People's Republic of China (China). The certificates are intended to meet the newly established exemption by the Chinese regulatory authority for animal testing on "non-special" or "normal" cosmetic products imported into China. Copies of these letters are attached as Appendix 1 for reference and further background.

Providing such a government issued compliance certificate for imported cosmetics – which China has indicated must be issued by the exporting countries' "own governments" – is intended to facilitate Canadian-based cosmetic manufacturers to maintain and EXPAND exports to China. Given the public, consumer, and industry concerns with the use of "animal testing" on cosmetic products, the ability to use this exemption is a critical issue for Canadian cosmetic manufacturers and exporters.

The problem, however, is that regulatory authorities throughout the world do not usually issue such "GMP certificates" for "cosmetic" products, nor do they specifically license cosmetic manufacturing facilities as they do for drug (and in Canada, for natural health product). GMP certificates for cosmetics are today provided primarily by third party providers – including Cosmetics Alliance Canada. However, such certificates would not qualify for the new Chinese exemption.

The manufacturing of cosmetic products in Canada is significant as Canada has been reported to be among the world's top 10 exporting jurisdictions for cosmetics[1]. Many Canadian manufacturing facilities are owned by, or manufacture for, major international brands and fulfill world mandates for production. Should Canadian based manufacturing sites be able to meet the requirements of the Chinese animal testing exemption, the advantage to Canadian-based cosmetic manufacturers would be significant in a very competitive international industry.

Cosmetics Alliance Canada has been engaged in detailed discussions over the past months with Health Canada officials from the Consumer and Hazardous Products Safety Directorate (CHPSD), the Non-Prescription and Natural Products Directorate (NNHPD), and the Regulatory Operations and Enforcement Branch (ROEB), as well as Global Affairs Canada (GAC). Reflecting these discussions, Cosmetic Alliance Canada is formally proposing the establishment by Health Canada of a voluntary certification program for identified cosmetic products ("non-special" or "normal" cosmetics as defined in China) intended to specifically facilitate the export of such products to China such that they qualify for China's exemption for animal testing.

[1] Conference Board of Canada (2014) – as cited by opencanada.org. Competing Globally: Canada's Hidden Success Stories. https://opencanada.org/canadas-hidden-export-gems/.

It is recognized and so proposed that such a program:

- Be limited to this purpose;
- Maintain the integrity and reputation of Health Canada as a regulator;
- Rely, where possible on the existing regulatory/oversight structures;
- Be based upon the applicant's voluntary consent to be part of the program, rather than any existing statutory authority;
- Include the applicant's voluntary consent for any verification procedures or requirements which Health Canada identifies and requires (where no such statutory authority exists); and
- Be as simple and efficient to administer as possible.

It is also recognized that at the time of writing, there is not yet an example of a successful "compliance certificate" being issued by a government that has been acceptable to Chinese authorities of which we are aware. Consequently, if it is the intention of Chinese authorities to make it essentially impossible to meet the exemption to their animal testing requirements on imports – which could be viewed as a non-tariff barrier to trade, then the provision of a reasonable and responsible certification program by Health Canada would strengthen any related trade action that might be contemplated.

PART 1: BACKGROUND

A. China's Requirement for Animal Testing on Imported Cosmetics & their New Exemption

Until recent regulatory reforms, the Chinese regulator (China's National Medicinal Products Administration or NMPA) did not treat domestic and imported "non-special" or "normal" (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 around the globe have abandoned due to the availability of non-animal alternatives.

Given the concern with animal testing in general, and certainly with the unnecessary requirements for animal testing for products exported to China – this requirement has made it difficult for cosmetic companies to export to China where their stated policy and actions have been to eliminate the use of animal testing. Consequently, the continuation of this Chinese requirement has been increasingly viewed as a non-tariff barrier to trade intended to discourage the sale of imported cosmetics to the benefit of domestically manufactured products, and so has been the focus of much industry outreach to the Chinese government over the past few years.

The recent adoption of a new cosmetic regulation by China does create an exemption to the animal testing requirements for imports, but rests on the conditions that:

1. Cosmetic imports "have GMP certificates issued by their own governments"; and

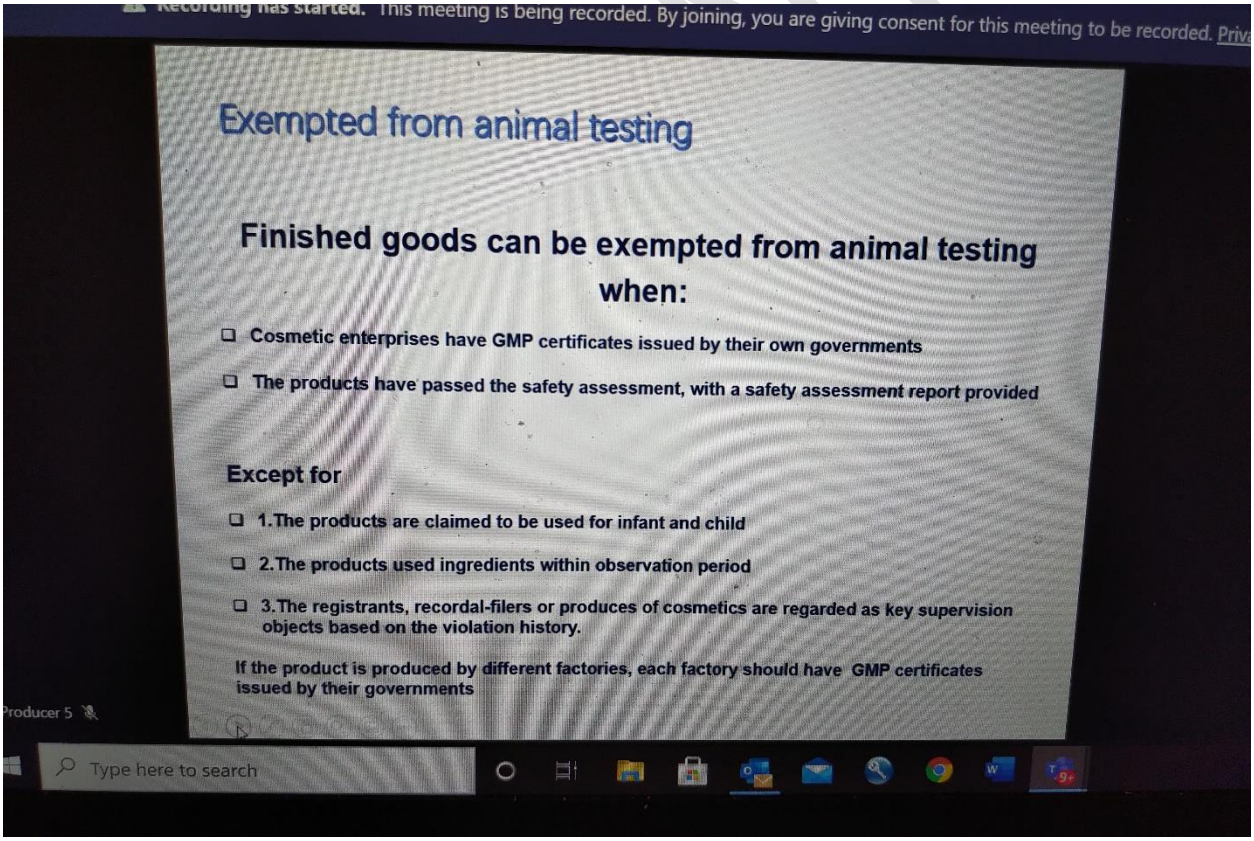
2. These products "have passed the safety assessment, with a safety assessment report provided".

This latest information comes from a presentation made by the Chinese regulatory authority at the Annual International Coordination of Cosmetic Regulation (ICCR) Joint Regulator-Industry Dialogue, which was recently held virtually on June 22nd, 2021, and in which the Chinese regulator participated as a formal observer (Health Canada being one of the original four founding jurisdictions and an on-going member).

It is also understood that the GMP compliance certificate issued by the exporting country substantiates that the product is recognized as being manufactured in accordance with a reasonable quality management standard as set out in Article 33 of the Chinese regulation.

The following is a screen shot of the relevant slide presented by Chinese regulators of which Health Canada will also be aware, due to their participation in the ICCR-15 meeting (Figure 1):

Figure 1: Excerpt from China NMPA Observer Presentation at the International Cooperation for Cosmetic Regulations 2021 Annual Meeting (ICCR-15)



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 jurisdiction's "own government" (which for Canadian manufacturers can be expected to be by 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 "GMP certificates" are currently typically issued by trade associations, including Cosmetics Alliance Canada, which WOULD NOT meet the Chinese requirements.

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

B. Impediments to Health Canada Issuing Compliance Certificates

Canada's *Cosmetic Regulations* under the *Food & Drugs Act*, as is the case in most jurisdictions, are NOT based on pre-market licensing but on notification to the regulator and in-market controls. Cosmetics manufacturers must comply with regulations mandated under the *Food & Drugs Act* and *Cosmetics Regulations* 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 conducts post-market surveillance, but it does not specifically license cosmetic manufacturing sites, nor does it have the statutory authority to do so. Cosmetic products are legally required to be "manufactured, prepared, preserved, packed and stored under sanitary conditions", and although cosmetic GMP's are recommended by Health Canada, they are not specifically mandated by Canadian regulation.

Consequently, as Health Canada officials have advised us, the current Canadian regulatory regime DOES NOT provide under its statutory authority for the issuance of such a quality management certificate for "cosmetics" as required by China. Thus any "compliance certificate program" would have to be voluntary and at the request of the manufacturer/exporter; likely be based on some existing regulatory oversight, knowledge, or experience which Health Canada already has or can easily acquire, and ultimately provide for any applicant to voluntarily provide the necessary legal authority for Health Canada to verify or support the legitimacy of the certificate issued (including the right of revocation, should it at any time be warranted).

C. Industry Issued GMP Certificates – Not Acceptable to Chinese Regulator

As Health Canada is aware, Cosmetics Alliance has for many years offered an Export Certificates Program to exporters (both CAC member and non-member companies). The program creates the legally binding certification documentation to verify compliance with Canadian regulations, standards, and practices (including cosmetic GMPs). Cosmetics Alliance Canada 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, the third-party GMP certificates that Cosmetics Alliance Canada provides WILL NOT meet the Chinese requirement for "government issued" GMP certificates. Furthermore, a recent letter provided by Health Canada (as drafted in 2020) recognizing our service has not proved suitable to meet the Chinese requirement. Without a "government issued' GMP certificate , Canadian-based manufactures would be left without a means to take advantage of this new exemption in China and avoid unnecessary animal testing.

PART 2: PROPOSAL

Following discussions with Health Canada officials from the Directorates outlined above, Cosmetics Alliance Canada wishes to propose the establishment of a voluntary Health Canada GMP Certificate Pilot Program for Exports of Canadian Manufactured "Non-Special" or "Normal" Cosmetics to China. The elements of this program should:

a) Be specific to what China defines as "non-special" or "normal" cosmetics and limited to such of these products that are intended or offered for export to China.

b) Be voluntary and limited to only those manufacturers and/or exporters who make application for the service.

c) Apply only to products manufactured in a manufacturing facility located within Canada.

d) Provide certification that the product meets one of the following quality standards (which would meet the requirements of Article 33 of the Chinese Regulation which is attached as Appendix 2):

   (i) The product(s) have been manufactured in a facility for which Health Canada has issued a Drug Establishment License (DEL) – which is in good standing - and have been manufactured pursuant to the required GMP's for such a license.

   NOTE: In practical terms, this may have very limited if any use as the GMP's for drugs are excessively prescriptive and costly for cosmetics (e.g., stability testing requirements, etc.) and so not likely to be applied to cosmetics even if the product is manufactured in a facility with a DEL.

   (ii) The product(s) has been manufactured in a facility for which Health Canada has issued a Natural Health Products Site License (SL) – which is in good standing – and have been manufactured pursuant to the GMP requirements for such a license.

   NOTE: This may, in practice, be the most useable provision as the large majority of

Canadian-based cosmetic manufacturers that have expressed interest in this program have SL's and the required GMP's for such a license are sufficiently outcome based to facilitate cosmetic manufacturing.

(iii) The product(s) has been manufactured in a facility for which an International Organization for Standardization (ISO) certificate has been issued in relation to ISO Standard 22716 (Cosmetic GMP's).

NOTE: Health Canada would verify that such a certificate was issued under the authority of the Standards Council of Canada. We understand that within the Medical Devices Program, Health Canada has a registry of recognized ISO auditors which it relies on for the certification of medical device manufacturing facilities. This list, or a similar one, recognizing ISO auditors for cosmetic manufacturing standards, should provide a sufficient chain of authority to support the issuance of a GMP compliance certificate by Health Canada on this basis.

e) As this program is not provided for in the regulatory authority of Health Canada, applicants must agree to and provide the necessary legal approval and authority for Health Canada to:

(i) Obtain all information required from the applicant necessary to issue a certificate;

(ii) Enter the premises of, inspect, obtain information, or do what is necessary to ascertain that the applicant complies with the standards for which the certificate has been issued;

(iii) Acknowledge the revocation of the certificate should at any time Health Canada determine, or have reasonable rounds to believe, that the applicant is not in compliance with the standard for which the certificate has been issued; and

(iv) Should an applicant withdraw their voluntary authority for Health Canada to inspect or conduct any verification that the product meets the certified standard, agree that Health Canada will revoke the certificate and declare it to be null and void.

f) Applicants must provide an affidavit to support any information provided to Health Canada in support of the certification which Health Canada may require. Cosmetics Alliance Canada is prepared to work with Health Canada to develop any specific wording to be reflected in any such affidavit(s).

g) Cosmetics Alliance Canada through its long-established Export Certificate Program would be prepared to work with Health Canada to manage the administrative intake and document preparation of applications for this certificate, thereby lessening any administrative burden on the Ministry. This service would be available to any applicant, whether a CAC member or not.

PART 3: URGENCY – PROTECTING AND GROWING CANADIAN EXPORTS TO CHINA

Cosmetics Alliance Canada members have advised that if a workable solution can be developed and accepted by Chinese authorities, it would create a significant opportunity for manufacturing cosmetics in Canada. This includes the shifting of production from non-Canadian 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 Health Canada and Global Affairs Canada.

PART 4: DETERMINING IF TRADE ACTIONS ARE WARRANTED

Although creating such a "GMP compliance certificate" should meet the requirements as outlined in the new Chinese regulations, there is no guarantee that it will be ultimately accepted by the Chinese regulator. As has been noted, China's requirements to access the exemption for animal testing on imported cosmetics does not match the regulatory frameworks in most of the world's exporting jurisdictions. The Chinese regulator is requiring a GMP certificate to be issued ONLY by the government of the exporting jurisdiction, which almost all governments do not now provide nor are empowered to do so. Third party certifications which are readily and reliably available are NOT acceptable under the Chinese exemption.

This position can be viewed as:

a. Being driven primarily by safety concerns and the belief that only a government GMP certification can be relied on;
b. A misunderstanding in how GMP certification for cosmetics works in most of the exporting jurisdictions; and/or
c. A means of creating a practical barrier to imported cosmetics (companies having to undertake unnecessary animal testing) to limit imported cosmetic products in the Chinese market or force international companies to manufacture in China for their market.

The efforts of Canada and other jurisdictions to develop a reasonable and responsible program for "government issued GMP certificates" will help to answer the question if China is using this requirement as a non-tariff barrier to trade. If so, it will be of assistance in informing any trade actions that may be considered.

PART 5: FINAL COMMENTS

In reference to the slide presented at ICCR by the Chinese regulator (Figure 1, above), Cosmetics Alliance Canada has noted the introduction of a second requirement that *"… products have passed the safety assessment, with a safety assessment report provided"*. As no further details have yet been provided in relation to this requirement, we will be exploring this further with our international industry colleagues and member companies. We can be expected to request the engagement and assistance of Health Canada and Global Affairs Canada should it be necessary to address this matter further, including seeking any clarifications from Chinese authorities, as appropriate.

We would submit, however, that it remains critical to develop the voluntary "GMP compliance certificate" program as soon as possible to either meet the requirements for the exemption, or to assess its intent to support possible outreach or actions by our trade representatives. Either course will be most helpful to the Canadian cosmetic manufacturing and export industry.

Cosmetics Alliance Canada stands ready to work with Health Canada and Global Affairs Canada in the ongoing interests of pursuing opportunities for Canadian manufacturing!

APPENDIX 1

Cosmetics Alliance Canada Letters to Ministers of Health and Small Business, Export Promotion, and International Trade

February 10, 2021

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

May 13, 2021

Urgent Follow-Up for Creation of New Export Certificate to Accommodate Export of Canadian Manufactured Cosmetics to China (Without Animal Testing)

COSMETICS ALLIANCE CANADA
The Voice of Canada's Personal Care Products Industry

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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)

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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 form 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.

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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

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May 13th, 2021

The Honourable Patty Hajdu, M.P.
Minister of Health
Health Canada
Tunney's Pasture
Ottawa, ON K1A 0K9

The Honourable Mary Ng, M.P.
Minister of Small Business, Export Promotion and International Trade
House of Commons
Ottawa, ON K1A 0A6

Dear Ministers,

Re: Urgent Follow-up for Creation of New Export Certificate to Accommodate Export of Canadian Manufactured Cosmetics to China (Without Animal Testing)

Request – URGENT Follow-up to our Letter of February 10th, 2021

We are writing as an urgent follow-up to our letter of February 10th, 2021, a copy of which is included for your reference, in which we requested 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.

As you will recall, this compliance certificate is required by China to exempt imported cosmetic products from its animal testing requirements and as such provides an important and significant opportunity for the Canadian cosmetic manufacturing industry.

Although we appreciate the quick response to our initial letter and the many meetings that we have now had with a multitude of Health Canada staff, the issue has yet to be resolved. This is creating a growing frustration among cosmetic manufacturers who see this as an excellent opportunity to increase manufacturing and exports for Canada.

Key Points for Consideration from Discussions with Health Canada Officials

In our discussions with Health Canada officials, the following key points have been identified and summarize the issues and options to move forward:

1. Health Canada **DOES NOT** currently require specific GMP's for the manufacturing of cosmetics, nor does it require the licencing of manufacturing facilities producing cosmetics (thereby providing limited means of addressing the issue under the existing regulatory framework).

2. However, Health Canada **DOES** issue **Drug Establishment Licences (DEL's)** for the manufacturing of non-prescription drugs, as well as **Site Licences (SL's)** for manufacturing sites making natural health products. These require the meeting of GMP standards and can involve inspection/audits by Health Canada inspectors.

3. As most Canadian manufacturing sites for cosmetics already have D.E.L.'s and/or S.L.'s, as they make cosmetic and other personal care products that are currently classified as "drugs" or "natural health products", using these existing licences should provide more than a sufficient basis for issuing a "compliance certificate" for "cosmetics" manufactured in these sites.

4. Additionally, Some Canadian cosmetic manufacturing sites are already certified as meeting the International Standards Organization (I.S.O.) standards for manufacturing cosmetics, with the certification process being conducted by an I.S.O. auditor recognized by the Government of Canada. This too should provide a regulatory basis for Health Canada issuing a "compliance certificate".

5. At the current time, the use of these options as the regulatory basis for Health Canada to issue a "compliance certificate" would address this issue for the majority of Canadian-based cosmetic manufacturing facilities and production capacity. Any further extension would depend upon the number of sites that do not meet any of these requirements and who would be interested in the opportunity. They can be addressed, if necessary, later. What is important is that the provisions that Health Canada can currently support from a regulatory oversight perspective be put in place on an **URGENT** basis.

Implementation Roadblock – Need for Decision

In our discussions with officials, it has become evident to us that a roadblock in implementing the required "compliance certificates" lies within the current administrative structures of Health Canada and which branch has responsibility for what.

The issuing of a "compliance certificate" for products defined under the *Food & Drugs Act* as "cosmetics" rests with the Healthy Environments and Consumer Safety Branch (HECS) which administers the *Cosmetic Regulations*. However, the oversight/compliance for manufacturers with D.E.L.'s and S.L.'s is with the Health Products and Food Branch (HPFB), which administers the *Drug* and *Natural Health Product Regulations*.

Consequently, one branch of Health Canada will have to rely on the work of another branch to issue such a "compliance certificate" for these cosmetics, and the decision to authorize this initiative will have to be made at a high level that crosses the two branches. Regrettably, none of the official who were assigned to work with us indicated that they had the authority to make such a decision and consequently we understand that they will be briefing senior officials as to this situation.

We would therefore urge that this matter be given the necessary attention at a senior enough level between the two branches to implement the solutions outlined above.

Urgency – Protecting and Growing Canadian Manufacturing Exports to China

As Canadian-based cosmetic manufacturers and exporters have advised, a workable solution will create a significant opportunity for expanding the manufacturing of cosmetics in Canada!

Importantly, this includes the shifting of production from facilities outside of Canada to Canadian sites so that products can be exported to China without animal testing requirements. This is surely an opportunity for which we must move on quickly to get in place the necessary "compliance certificates" required under the new Chinese regulations.

As China was scheduled to implement its new regulations this May 1st, time is of the essence for Canadian manufacturers and exporters!

Contact Information

Diane Kozak of my office is available to arrange any virtual meetings which you may require. 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 having a solution in place as soon as possible to allow Canadian based cosmetic manufacturers to take full advantage of this opportunity.

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

APPENDIX 2

Provisions for Management of Cosmetic Registration and Notification Dossiers

Article 33 Excerpt from Chinese Regulation
(unofficial version – English translation – ChemLink)

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Chapter III Requirements for Registration and Notification Documents

Article 33 The product testing report of registered or notified products shall be issued by the cosmetics registration and notification testing institution, which shall comply with the provisions of relevant laws and regulations such as STSC, “Working Rules for Cosmetic Registration and Notification Testing”, *etc*.

(I) Product testing reports include microbiological and physical and chemical testing, toxicological testing, human safety testing reports and human efficacy testing reports, *etc*.

1. The tested samples in the product testing report shall be products with the same product name and batch number.

2. The product information stated in the product testing report shall be consistent with the information related to the registered or notified product. Information such as product name, enterprise name and other information in the product testing report that does not affect the testing results are consistent with the registration and notification information due to the name change and other reasons, it shall be explained, and an application form for changing the testing report and a supplementary testing report or correction letter issued by the testing institution shall be submitted.

3. If multiple production enterprises produce the same product, a complete product testing report of samples from one production enterprise shall be provided, and microbiological and physical and chemical testing reports of samples from other production enterprises shall be submitted.

4. Multi-color series general cosmetics sampled for toxicological test according to the “Working Rules for Cosmetic Registration and Notification Testing” can be notified as a group of products, and each product shall be attached with a list of series products, a list of basic formulas and colorants, and a list of sampled products.

5. Cosmetics claiming new efficacy shall be tested in accordance with the “Working Rules for Cosmetic Registration and Notification Testing” and relevant technical regulation documents.

(II) If the production enterprises of general cosmetics have obtained the relevant qualification certification of production quality management system issued by the competent government department of the country (region) where it is located, and the product safety risk assessment result can fully confirm the product safety, it may be exempted from submitting toxicological

testing report of the product, except for the following circumstances:

1. The product claims to be used by infants and children;

2. The product uses new cosmetic ingredients that are still under safety monitoring;

3. According to the results of quantitative grading, the notification applicant, domestic responsible person and production enterprise are listed as key regulatory objects.

If there are multiple production enterprises, and all production enterprises have obtained the relevant qualification certificates of production quality management system issued by the competent government departments of the countries (regions) where they are respectively located, the toxicological test reports may be exempted.

(III) When applying for registration of special cosmetics, a human efficacy testing report that complies with the relevant regulations on cosmetic efficacy claim evaluation shall be submitted.

1. The efficacy testing report of special cosmetic claims shall be issued by the cosmetics registration and notification testing institution.

2. Multi-color series sunscreen cosmetics sampled for human efficacy test according to the “Working Rules for Cosmetic Registration and Notification Testing” can be applied for registration as a group of products at the same time. Each product document shall be accompanied with a list of series products, a list of basic formulas and colorants, and a list of sampled products.

Article 34 The registration applicant and notification applicant shall carry out product safety assessments in accordance with the requirements of relevant technical guidelines for cosmetic safety assessments and form the product safety assessment reports.

Cosmetics that must be used in conjunction with instruments or tools (except brushes, air cushions, hair perming tools, *etc*. which only assist in rubbing) shall be assessed for their safety under the conditions of use with instruments or tools; in addition, explanatory documents on whether the instrument or tool has cosmetic function, whether it participates in the reproduction process of cosmetics, whether it changes the mechanism of action between products and skin, *etc*. shall also be provided.

Article 35 Cosmetic containing two or more independent formulas that must be used together or whose packaging containers are inseparable, the formulas shall be filled out separately,