Regulatory Essentials – July 8, 2020

Cosmetics Alliance Updates

Cosmetics Alliance Interactive Training Session

First Series Focuses on NHP Market Access

CA's first series of interactive training sessions introduces natural health products (NHPs) and the regulatory requirements for market access.

The first session was held on June 10th and provided an overview on Product Licensing.

Post-Licensing Changes Overview

Date: Wednesday, July 8, 2020

Time: 2:00 pm - 3:30 pm

Cost: Member: $250 Non-Member: $395

Learn and Understand:

- The difference between a notification, amendment, and fundamental change
- What is required for each
- How Health Canada processes these types of changes
- Which types require approval from Health Canada prior to implementation

Each session will include exercises, a quiz and a Q&A session.

Training Certificates are issued for your records to each individual successfully completing the quiz.

Individual logins are required for each participant to obtain a training certificate.

Register

Business in Quebec? We Need Your Input!

Does your Company have an Establishment or Place of Business in Québec? If So, Please Help Us Access Government Funds to Support Our Industry!

Cosmetics Alliance is partnering with CoeffiScience to conduct an in-depth analysis of specific training and human resources needs for the cosmetics sector in Québec. Identifying the issues will help guide the investments made by the Government of Québec over the next few years to support our industry.

We need your help! If you have an establishment or place of business in Québec, please click on the survey links below to add your voice.

Data gathered will be compiled into a report for the Québec government and will help us access funds to support training for your company. All company representatives are welcome and encouraged to participate.

NOTE: In order to benefit from the funding, a company must have an establishment or a place of business in Québec. For example, a salesforce that does not have ties to an office in the province would not be able to benefit from this initiative.

Please be assured that your responses will be treated confidentially and that no personally identifiable information will be shared with any third party.

SURVEYS:

Please complete the target group surveys that apply to your role and/or your company. The surveys are brief and should not take much of your time. (The surveys are in French. English translation is provided by clicking "English" at the top right.)

HR, Training Professionals, etc

https://forms.gle/aPnq2h276jyDz4KF8

Operations, Manufacturing, Warehousing, Formulators, Distribution, Regulatory, Compliance, Quantity Control & Assurance, etc

https://forms.gle/QFw8xNvC5cw3paEh9

General Management & Senior Executives, etc

https://forms.gle/SEJtybXSfXR2XexY9

Retail, Sales, Marketing, Promotion, Advertising, Communications, Creative, Social Media, etc

https://forms.gle/dKeEha7vNiQtFrFw7

More About the Project

Invest in the workforce of tomorrow! Labor issues are a direct threat to the development and profitability of our industry. To cope with this, the Québec government wishes to invest in sectoral solutions aimed at developing a better adapted and more efficient work force. This online survey will help identify the specific workforce needs of the Quebec cosmetics industry. This is a first step towards a collective project for the development of our human resources.

More About CoeffiScience

CoeffiScience is entirely dedicated to workforce development. Administered by businesses and workers, the Committee analyzes the needs of industry and implements government assistance programs for the development of businesses and workers.

Within its mandate, CoeffiScience:

• Acts in terms of training;

• Helps in structuring internal training practices;

• Promotes careers to the next generation of workers;

• Helps in the structuring of human resources;

• Analyzes, investigates and disseminates relevant information on the industry;

• Promotes concerted action between local stakeholders.

Health Updates

Health Canada Revises Rules on Quarantine & Re-testing, Sampling

In a late afternoon teleconference with stakeholders, Health Canada confirmed that they will be issuing a DEL Bulletin outlining further changes to provide for the **full implementation** of the benefits of CUSMA for our industry effective next Wednesday, July 1st. These were secured through a concerted effort by the CA team over the past two weeks after the release of Health Canada's initial plans did not incorporate the full scope of the CUSMA provisions.

To summarize, these changes **allow for the full range of products included in the scope of Appendix 1 of CUSMA's** Cosmetics Annex to benefit from the **elimination of "quarantine and confirmatory re-testing"**, as well as **allow these products to be included in the new rules for sampling**. The original Health Canada implementation plans essentially applied to only monographed products and could have been expected to result in a trade complaint under CUSMA.

More specifically, the revisions will:

1. Re-configure the *List for Non-prescription Drugs: With Respect to the Distribution of Samples; and for Non-prescription Drugs for Which the Testing Requirements Set out in Subsections c.02.019 (1) and (2) of the Food and Drug Regulations Do Not Apply* such that it includes all products set out in the CUSMA scope rather than just monographed products.
2. Re-configure *List A: Certain Non-prescription Drugs for Distribution as Samples* to also allow for the inclusion of the full CUSMA scope of products and not just monographed products.
3. Re-configure *List A: Certain Natural Health Products for Distribution as Samples* to also allow for the full scope of CUSMA defined products. As this revision requires a regulatory amendment which cannot be made before the July 1st implementation date, these products will be exempt from sampling prohibitions and enforcement actions will be de-prioritized. We understand that this interim measure will be in place until such time that the list referenced in the regulatory amendments has been formally updated.

Any company or their legal representative who may have questions, or require clarity, will be invited to contact a Health Canada representative such that no company is denied the benefit of these new CUSMA provisions as of July 1st, 2020. The CA team will also be available to answer any of your questions.

The full benefits of CUSMA's Cosmetics Products Annex were secured through the coordinated efforts of Cosmetics Alliance Canada, the U.S. Personal Care Products Council (PCPC) and the

Mexican Cosmetics Industry Association (CANIPEC) during the two-year long NAFTA negotiations.

It is estimated that the savings from the elimination of the "quarantine and re-testing" provisions on these "cosmetic-like D.I.N. products" is some $100K per year per SKU.

CA would like to thank Health Canada Deputy Minister Dr. Stephen Lucas and his teams at the Natural and Non-prescription Drug Directorate (NNHPD) and the Regional Operations and Enforcement Branch (ROEB) for their efforts and engagement with our CA team over the past two weeks. Through these combined efforts we were able to resolve this issue and ensure that there would not be a trade complaint under CUSMA after July 1st. We would also like to also thank our colleagues at the U.S. PCPC who worked closely with us to manage the issue with U.S. trade officials.

CA will provide more details once the formal materials are posted by Health Canada.

For any questions or comments, please contact your CA Team.

CUSMA Implementation – Health Canada Formal Notice of Further Guidance

As a follow-up to our member update last Friday, June 26th and our newsletter from earlier today, we are forwarding the following two communications from Health Canada formally announcing revisions to their CUSMA implementation:

1. DEL Bulletin No. 89 *Coming into force of Regulatory Amendments* (EN/FR) which provides for the implementation of the CUSMA provisions for **ALL** qualifying D.I.N. products which are outlined in the enclosed table. This applies **BOTH** to the elimination of quarantine and confirmatory re-testing requirements (thereby allowing direct shipment to wholesalers/retailers), and the provision of samples under the new regulations.
2. Update and Next Steps on the implementation of the Canada-United States-Mexico Agreement (CUSMA) / Mise à jour et prochaines étapes sur la mise en œuvre de l'accord Canada-États-Unis-Mexique (ACEUM) which we have been advised will be sent to all NPN and DIN holders over the coming days and no later than by close of business on July 3rd. It is intended to provide an update as to the further amendments and interim measures being taken to ensure full compliance with CUSMA effective July 1st. This includes adding a table of natural health products which will be eligible for the new sampling provisions.

Both documents are consistent with the information as previously reported. Should any company or their legal counsel require further clarification, please contact your CA team or the Health Canada contacts identified in the Health Canada Update.

CA would also encourage you to register for the Health Canada Information Session scheduled for July 22nd. The registration information is included in the *Update and Next Steps* document. Please register early as participants are limited to 200.

Should you have any questions, please contact your CA team at ca@cosmeticsalliance.ca.

DEL Bulletin LEPP No. 88 Enhanced guidance to support submission of proposals for inclusion on List of Drugs for Exceptional Import and Sale

On April 6, 2020, Health Canada wrote to stakeholders in DEL Bulletin LEPP No. 82 to provide information about the *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19*, which was signed by the Minister of Health on March 30, 2020. The interim order (IO) allows certain drugs that may not fully meet regulatory requirements to be imported and sold in Canada.

The purpose of this DEL bulletin is to provide additional guidance to stakeholders.

Revised Form to Submit Proposals

In order to more efficiently gather information on proposals for inclusion of a drug on *List of Drugs for Exceptional Importation and Sale*, Health Canada has revised the form used to submit proposals. As outlined in DEL Bulletin LEPP No 82, in order to add a drug in a Tier 3 shortage to the List of Drugs for Exceptional Importation and Sale, Canadian importers are required to fill out a standard form and email it to hc.ds-iopropau-pm.sc@canada.ca. The new form was posted on the webpage that contains guidance for industry on exceptional importation. For your reference, this revised form is also attached to this email.

Accessibility of Information to Support Safe Use of Designated Drugs

Canadian importers must take steps to ensure that information is accessible to Canadians that supports the safe use of the drug. Canadian importers are expected to prepare and implement a risk communications plan to meet this requirement, which would include taking steps to ensure information is accessible in both official languages. Of note, Canadian importers are expected to provide a risk communications plan in their proposal that outlines how they intend to ensure accessibility of information that supports safe use of the drug.

Upon importation, Canadian importers are required to ensure information is available in a manner that supports safe use of the drug. Canadian importers are expected to work closely with the Drug Shortages Unit and, where needed, the Marketed Health Products Directorate on the review and implementation of a risk communications plan to ensure compliance with this requirement.

Drug Establishment Licence (DEL) Amendments

Companies that intend to submit a proposal for inclusion of a drug on the *List of Drugs for Exceptional Importation and Sale* are asked to communicate directly with the Drug Shortages Unit at hc.ds-iopropau-pm.sc@canada.ca. Once proposals are submitted to the Drug Shortages Unit, the following will occur:

- The Drug Shortage Unit will assess the proposal, including the DEL status of the company, and determine what drugs will be added to the List of Drugs for Exceptional Importation and Sale.

- If DEL amendments are required to import the proposed drug, the Drug Establishment Licensing Unit will contact the company directly regarding the preparation of a DEL amendment application. This will facilitate expediting DEL amendments should the proposal be accepted, and the drug be added to the List of Drugs for Exceptional Importation and Sale.

Note: Unless the Drug Establishment Licensing Unit directly contacts companies accordingly, companies should not pre-emptively submit a DEL amendment application for drugs pertaining to this IO.

For any questions regarding DEL amendment applications for drugs pertaining to this IO, please contact hc.del.questions-leppp.sc@canada.ca

DEL Bulletin No.88 – EN

DEL Bulletin No.88 - FR

Environmental Updates

European Commission Data on Prostaglandins

The European Commission published the following call for data on prostaglandins: https://ec.europa.eu/growth/content/call-data-prostaglandins-and-their-analogues-used-cosmetic-products_en

They add the following:

The Commission has concerns about the use of prostaglandins and their analogues in cosmetic products. Several EU countries recorded serious undesirable effects caused by the use of cosmetic products for eyelash growth containing prostaglandins and/or its analogues. There are also indications that prostaglandins and their analogues are used and placed on some EU country markets as active ingredients in medicinal products. See entry 3.3.5 of the borderline products manual for more.

We will mandate the EU Scientific Committee for the Safety of Consumers (SCCS) to assess the safety of the above mentioned cosmetic ingredients. In preparation, we invite interested parties to submit relevant scientific information on the safety of prostaglandins and their analogues in line with the requirements. See the following non-exhaustive list

- *Prostaglandins (CAS no. 13345-50-1, EC No. 634-333-3),*
- *Isopropyl Cloprostenate (CAS no.157283-66-4,)*
- *Bimatoprost (CAS no. 155206-00-1),*
- *Ethyl Tafluprostamide (INN name Tafluprost, CAS: 209860-87-7),*
- *Other synthetic analogues of a prostaglandin (see Table 1 below).*

Environment & Climate Change Canada's Risk Assessment Publications Plan for July-September 2020

In the early stages of the pandemic, Environment and Climate Change Canada have restricted Canada Gazette publications to COVID-19-related notices, urgent notices, or notices that met a statutory requirement. As a result, screening assessment reports and risk management documents have not been published on Canada.ca since March 14, 2020. During this time period, the Chemical Management Program continued to progress on the development of materials for publication.

As of May 19, 2020, the Canada Gazette has resumed its normal operations. As such, publications on chemical substances webpages are expected to resume in the coming weeks.

Cosmetics Alliance has have been working behind the scenes independently and with CEPA ICG to provide input on a meaningful path forward to manage these publications in a predictable, transparent, but reasonable way. Government officials have confirmed their intent to continue to be flexible particularly in their expectations on stakeholder engagement on CMP publications to allow for flexibilities in corresponding timelines to enable meaningful stakeholder input.

The Chemical Management Program has shared their publication plan below from July to September 2020, to help stakeholders anticipate and prepare for publications of interest. Exact dates for the publications are not provided however this gives a general idea on the publications to be released. If you have any questions for concerns please reach to your CA Regulatory Team.

Publications targeted for July-September 2020
Alkanolamines and Fatty Alkanolamides Group DSAR[a]
Antimony-containing Substances Group FSAR[b]
Aromatic Amines Group DSAR[a]
Epoxides and Glycidyl Ethers Group FSAR[b]
Fatty Acids and Derivatives Group FSAR[b]
Napthalene Sulfonic Acids Group DSAR[a]
Nitro Musks Group FSAR[b]
Petroleum Base Oils Group FSAR[b]
Petroleum Coke DSAR[a]
Phthalates FSAR[b]
Pigments and Dyes Group FSAR[b]
Poly(amines) Group FSAR[b]
Silver DSAR[a]
Sulfurized Isobutylene DSAR[a]
Thallium DSAR[a]
TMSS DSAR[a]

[a] Draft Screening Assessment Reports (DSAR) presenting information on health and ecological considerations and, where criteria under s. 64 are proposed to be met, Risk Management Scope documents.

[b] Final Screening Assessment Reports (FSAR) presenting information on health and ecological considerations and, where criteria under s. 64 are met, Risk Management Approach documents.

Note: Group names are not final and may change.

Various Publications under the Chemicals Management Plan

Performance Measurement
The performance measurement evaluations for lead, PBDEs, BPA-ecological component and mercury have been published.

https://www.canada.ca/en/health-canada/services/chemical-substances/performance-measurement-toxic-substances.html#pmer

Sulfurized Isobutylene
The Draft Screening Assessment for Sulfurized isobutylene was published for a 60-day public comment period ending on September 2, 2020.

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/sulfurized-isobutylene.html

Naphthalene Sulfonic Acids and Salts Group
The Draft Screening Assessment for the Naphthalene Sulfonic Acids and Salts Group was published for a 60-day public comment period ending on September 2, 2020.

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/naphthalene-sulfonic-acids-salts-group.html

Release of draft (step 2) ICH guidance: Q3C(R8): Impurities: Residual solvents

The above referenced draft guidance was released by the International Council for Harmonisation (ICH) Assembly for consultation and is being posted on the ICH website for information and comment in accordance with Step 2 of the ICH process.

Please note that draft guidance documents are only available in English until finalised by the ICH. It is also important to note that amendments to draft documents may occur as a result of regulatory consultations and subsequent deliberations within the ICH.

All comments forwarded to Health Canada will be transmitted to the ICH as is, with the disclaimer that they are provided for information and do not necessarily represent the views of Health Canada, except as specifically indicated in separate comments.

Comments provided to Health Canada should be submitted by Friday July 31, 2020 in order to allow sufficient time for their assessment and subsequent transmission to the ICH.

Comments should be directed to:

Health Canada - ICH Coordinator
E-mail: hc.ich.sc@canada.ca

Post-Consumer Waste Update

Blue Box Program Transition Plan: Consultation Q&As and Feedback Reminder

The questions and answers from the consultation webinars have now been posted alongside the webinar recordings and presentation on the Stewardship Ontario website.

If you have any questions while reviewing the materials, please email consultation@stewardshipontario.ca. Answers will be provided via email and added to the question and answer document.

Please submit written feedback on Stewardship Ontario's transition proposals by **July 15, 2020** to consultation@stewardshipontario.ca**.**

All feedback will be included in the consultation report submitted to the Resource Productivity and Recovery Authority (RPRA) along with the Transition Plan by the Minister's August 31, 2020 deadline.

Participate in RPRA's Proposed 2020 Registry Fees Consultation

The Authority is consulting on its proposed 2020 Registry fees for tires, batteries and electronics. These are fees that registrants pay to the Authority to cover the Authority's costs related to building and operating the Registry, and compliance and enforcement activities.

We are hosting two webinars to describe the methodology used to calculate the proposed fees and gain feedback from registrants and other interested stakeholders. Learn more and sign up for a webinar.

Batteries now managed under individual producer responsibility framework

On June 30, 2020, the waste recovery program for single-use batteries operated by Stewardship Ontario ended. As of July 1, 2020, both single-use and rechargeable batteries became the second material, after tires, to be managed under Ontario's individual producer responsibility regulatory framework. RPRA is the regulator mandated by the Ontario government to oversee the new framework.