# Regulatory Essentials – December 4, 2019

## Cosmetics Alliance Updates

Last Chance to Register for the Fall Regulatory Workshop!

Date: December 12, 2019

Hear from government officials and Cosmetics Alliance staff on issues that will directly affect your business.

Important topics that will be covered:

- Sunscreen Pilot & Expansion
- NHPID Process
- Hotlist Updates / Process
- Updates to PLL, Compliance & Enforcement Approach
- Self Care Framework Updates from Summer & Fall
- Upcoming changes to Cost Recovery program for cosmetic-like drugs
- How Health Canada's Food and Drug Act Liaison Office can assist in facilitating conversations with officials

Register

Cosmetic Labelling 101 Introduction to Cosmetic Labelling for Canada

December 19, 2019

2:00 - 3:30 pm plus1/2 h quiz

Designed for New Employees and New Cosmetics Alliance Members

Objectives

- Lean the language of cosmetics in Canada
- Overview of the Cosmetic Labelling Regulations
- Learn how other Canadian regulations apply to cosmetics
- Understand how these regulations interact with each other

Register

**Only those electronically registered will be able to take the quiz and receive a training certificate. Limited spaces available!**

## Health Updates

Final U.S. Sunscreen Monograph Delayed

The deadline for the FDA to finalize the Sunscreen Monograph was November 26, 2019. During the consultation period on the Proposed Rule in June of this year, the FDA received more than 20,000 stakeholder comments and is required to consider all relevant comments received during the rulemaking process. Given the volume of comments, the FDA published a notice that

the final rule will not be completed until September 2020. Until this time, the current Monograph remains in place.

You may recall that Cosmetics Alliance submitted comments to the FDA stressing the need for harmonization, where possible with the Canadian Sunscreen Monographs given the agreement of both countries to the Cosmetics Annex of the Canada-United States-Mexico Agreement (CUSMA/USMCA) and the trade implications of varying standards.

Updates on Changes to the Cosmetic Ingredient Hotlist

Earlier this year, Health Canada consulted on proposed updates to the Cosmetic Ingredient Hotlist. There were many member concerns with the proposed changes to the labelling of products containing Eucalyptus Oil. We are pleased to report that due to CA discussions with Health Canada, industry engagement and the volume of comments received on this specific proposal, HC will again be consulting on this ingredient in their 2020 round of consultation. Health Canada has issued a chart of responses to the comments received. Regarding Eucalyptus Oil, it indicates:

The update for Eucalyptus Oil will not be included in the current round of Hotlist updates. At this time a second Consultation is planned in spring 2020 but you may provide Health Canada with additional information before the formal consultation is posted. If at any time Health Canada receives information that indicates the potential for a serious risk, the Program will bypass the general Hotlist update approach and take any immediate action necessary.

This provides industry with the opportunity to submit additional information to HC during the pre-consultation and official consultation phases of Hotlist updates in 2020. It is important to note that in their response, Health Canada says “Cautionary statements are being reviewed. Revised cautionary statements should be provided in a second consultation in 2020.” We are hopeful that the 2020 proposal is more reflective of current science and industry practices as was stressed in CA’s comments.

Cosmetics Alliance did not object to the other changes as proposed with the exception of some administrative clarifications.

We do not know the exact date of when the Hotlist updates will be posted, but we anticipate it will be done before the end of the year. Once it is online, it will be communicated through Health Canada’s Cosmaliste and in the Cosmetics Alliance Regulatory Essentials.

DEL Bulletin No. 62 Management of Applications and Performance for Drug Establishment Licences (GUI-0217)

Health Canada is pleased to share the Management of Applications and Performance for Drug Establishment Licences (GUI-0127). GUI-0127 will be implemented on April 1st, 2020 and is being shared with you now so that you have time to prepare for its implementation. GUI-0127 contains best practices that can and should be used as a reference immediately.

GUI-0127 outlines:

- the responsibilities of applicants in the Drug Establishment Licence (DEL) application process
- how Health Canada manages DEL applications,

- DEL pause-the-clock policy
- new process improvements for the review of DEL applications, and
- policies that are currently applicable and were previously communicated in DEL bulletins, including:
    - implementation of the new evidence required by date (NERBY), DEL bulletin #1, and
    - issuance practices, bulletin #51

Please take the time to review the guide and let us know if you have any questions at regulatory@cosmeticsalliance.ca.

GUI-0217 DEL MAP - EN

GUI -0217 DEL MAP - FR

Key Guidance Documents for Drug Establishment Licenses

The Resource Management and Operations Branch has a Funding and Fess site on the Health Canada website where important information about Cost Recovery can be found. The website will be updated periodically with guidance documents pertaining to Cost Recovery and Drug Establishment Licences as well. Guidance documents such as Fees for the Review of Human Drugs & Disinfectant Submission and Applications, Fees for the Right to Sell Drugs and more can be found here.

Cost Recovery Training Session

On Thursday, November 28, 2019, the Resource Management and Operations Directorate hosted a Cost Recovery Training Session pertaining to Drugs (Human and Veterinary) (Establishment Licence Fees) Training Session. Below are the key points from the session. The presentations are linked below.

- Applicants need to look at the new GUI-0127: Guidance on Drug Establishment Licences and Associated Fees for information on the DEL application process and changes that relate to cost recovery that come into effect in April 2020
- There is a 4-year implementation to the fees and changes will be published in *Canada Gazette, Part I* every year
- Changes to the Pause-the-Clock process – the length of the pause has been increased from 20 to 30 business days and there will now be 2 opportunities for applicants to address deficiencies, overall the process will be more predictable
- The 250-day performance standard is still in place except for applications that require a HC foreign site inspection. For Table A only changes, the performance standard is 20 days.
- DEL Issuance Policy – when amending or adding a site applicant need to do each one separately with the exception of Table A which needs to include all API sites as per the attestation. This will allow HC to track and report the performance standard for each type of application and plan for the future
- If companies have sites to remove from their DEL, this needs to be done prior to the fee review on April 1, 2020 or else they will be included in the invoice, payment need to be made within 30 days of issuance of invoice
- HC will be posting a fee calculator closer to April 2020

Fees for the Review of Drugs

DEL Presentation

**Environmental Updates**

Report on Human Biomonitoring of Environmental Chemicals in Canada

The Fifth Report of the Human Biomonitoring of Environmental Chemicals in Canada was released on November 13. This technical report provides biomonitoring results from the fifth cycle (2016-2017) of the Canadian Health Measures Survey (CHMS). The report is currently available online at canada.ca/biomonitoring. Data for 99 environmental chemicals was collected, this included the first hair data for 25 metals and trace elements.

Of note to the personal care products industry are the following results:

- Overall blood lead levels have decreased almost 30% between 2007 and 2017
- Paraben levels in urine have decreased 33% from 2012 to 2017
- Phthalates levels in urine have seen a 40-50% decrease since 2009

This information is used in evaluating the success of chemical management measures and to determine if additional measures are necessary.

CHMS C5 Briefing – EN

CHMS C5 Briefing - FR

**Post – Consumer Waste Updates**

Presentation Now Posted - Ontario Government Webinar on Blue Box Transition

The November 27, 2019 Government of Ontario webinar presentation on the future transition of the Blue Box Program to full producer responsibility is now available. The next stage is the development of a regulation under the Resource Recovery and Circular Economy Act as well as any regulatory amendments necessary to end municipalities' obligation to provide Blue Box services. The webinar explained how you can take part in the development of the new regulation. The Government will be consulting in the Spring of 2020 on policy options for the new regulation, with the draft regulation anticipated for Fall 2020. The goal is a final regulation early in 2021. Transition to the new producer responsibility program will then occur over three years from 2023 through 2025. Transitioning the Blue Box program to full producer responsibility will be a multi-stage process that will involve many future opportunities for stakeholder input.

Comment Deadline - CCME Consultation on Consistent EPR policies for plastics

CCME is seeking input from stakeholders and other interested parties to inform the development of consistent extended producer responsibility (EPR) policies for plastics across Canada. CCME has posted a discussion paper that provides context regarding current EPR policies in Canada and poses strategic questions on how governments can improve consistency across jurisdictions. Please click here to view the Discussion Paper: Guidance to facilitate consistent extender producer responsibility polices for plastics. The discussion paper contains a link to an online form to collect comments and feedback on the questions posed in the

discussion paper. Comments will be received until December 5, 2019. Please contact Natalie James at njames@ccme.ca or (204) 948-3025 if you require more information.