# Regulatory Essentials – November 11, 2020

## Cosmetics Alliance Update

Last Session in this 3 Part NHP Series - Natural Health Product Good Manufacturing Practices

Date: Wednesday, November 25, 2020

Time: 2:00 pm - 3:30 pm EST

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

Learn and Understand:

- What the elements of GMPs are
- What is required for GMPs?
- Product quality specifications and testing requirements

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

Webinar – Top Themes Shaping Beauty in a Post-COVID-19 World

Discussion Points:

Economic and lifestyle shifts from COVID-19 are changing beauty consumption, spend and routines. Consumer behaviors formed during the pandemic will drive product and shopping preferences. Euromonitor International identified the top themes impacting consumer markets as a result of COVID-19. This webinar identifies which themes will accelerate within the beauty industry, microtrends on the rise and the expected industry outlook to help players navigate what's next globally and in the Canadian Market.

Speaker:

Evelyn Rodriguez is a senior analyst at Euromonitor International. Based out of Chicago, Evelyn analyses the beauty and personal care industries to help organisations make strategic business decisions. She provides insight into consumer trends, competition and growth opportunities across the fast-moving consumer goods space.

Date: November 19

Time: 1:00 pm - 1:45 pm

Register

## Health Updates

Important Changes to Site Licenses – Elimination of Backlog

- If your site licence expiry date was extended or
- If you site licence is expiring or
- If you are currently working on your site licence activities

The following information is important to you.

There is no backlog for new, amendment or notification applications.

A new web-based site licence application is being released on November 12th, 2020 to increase operational efficiencies.

HOW YOU CAN HELP WITH THE BACKLOG

A new web-based site licence application form will be released November 12th, therefore if you are working on your site licence package and can wait to submit your application until after the new form is released, migrate to the new form, as long as you can still meet the 30 day deadline for a renewal.

- Do not submit paper-based applications, they will not be accepted after November 26th.
- Avoid submitting deficient applications. Applications will be refused if:
- There is not site licence application form included.
- If there is no GMP evidence included for any site which requires GMP evidence
- If any portion of the application is in neither French nor English
- You are unable to respond to an information request notice (IRN)
- Only include sites which are active sites.
- Withdraw inactive sites if an application has already been submitted
- Separate amendments and notifications from site licence renewal packages

Site Licence Renewals – Extended Validity Period

For those sites which could take advantage of the extended period of validity (i.e. until December 1st):

- You were requested to continue to submit renewals 30 days prior to the expiration date.
- Some renewals have not been received to-date, if you have extraordinary reasons as to why you were unable to submit, a contact person has been identified in the announcement
- Site License Renewals
- Renewals are still required to be submitted 30 days prior to their expiry dates
- The target for eliminating the backlog is December 1st, 2020
- Other site licence activities (new, amendments and notification) will continue to be processed while the backlog is being eliminated
- The period of validity for foreign sites with no identified issues will be extended until further notice
- Foreign site reference number applications (FSRN) not linked to an importer will be low priority and will not meet the service standard
- New foreign site amendments and FSRNs that do not contain a regulatory inspection report will not be reviewed within the service standard

Risk Based Approach to Site Licences – EN

Risk Based Approach to Site Licenses – FR

Mandatory Cyclical Enforcement Inspection activity – Diffusers

Recently, Cosmetics Alliance has become aware of a Mandatory Cyclical Enforcement Inspection activity that Consumer Products and Controlled Substances Directorate has started. They are focussing on scented room Diffusers using wicks that are actively being sold in the Canadian marketplace to determine their compliance with applicable legislation such as labelling, formulation, etc. Diffuser products are regulated as Consumer Chemical products and is not part of the personal care product industry. This is a courtesy notice as many of CA members do manufacturer a vast variety of consumer products as well.

Applying for a Drug Identification Number (DIN) for a disinfectant drug during the COVID-19 pandemic

The Natural and Non-prescription Health Products Directorate (NNHPD) released a new publication of Applying for a Drug Identification Number (DIN) for a Disinfectant Drug during the COVID-19 Pandemic**.** This document provides additional information on how to apply for a DIN and clarifies existing processes and guidance for a disinfectant drug product regulated under the Food and Drug Regulations.

**Environmental Updates**

Import and Manufacturing Requirements for New Substances

On October 28, Environment & Climate Change Canada released the import and manufacturing requirements of Living organisms (such as bacteria and yeasts) and animate products of biotechnology (such as enzymes) are commonly used in a variety of industries* including:

- Biocatalysis
- Bioremediation
- Mining
- Wastewater Treatment
- Pulp and Paper Processing
- Biofuel
- Medical / Pharmaceutical
- Food

***Please note that this list is not exhaustive***

If you import or manufacture (produce, grow, develop) a new substance or a product containing a new substance (such as flocculation agents, effluent treatment agents, enzymes or bioremediation products) then you must ensure that these new substances have been assessed for potential risk to the environment and human health, as required by the *New Substances Notification Regulations (Organisms).*

The attached factsheet contains more information concerning what “new living organisms” are and provides information about notification requirements for the manufacture and import of new substances into Canada.

Also attached, is a Business Information Form. Please complete the form so that ECCC can provide you with updates on the *New Substances Notification Regulations (Organisms)*.

Business Information Form

Fact Sheet – EN

Fact Sheet - FR

Draft Screening Assessment for Coumarin Published

Environment and Climate Change Canada released the Draft Screening Assessment of 2H-1-Benzopyran-2-one, 7-(diethylamino)-4-methyl-, also referred to as Coumarin 1 on October 30. It is proposed to conclude that this substance may be harmful to human health and meets the criteria under section 64(c) of the *Canadian Environmental Protection Act, 1999* (CEPA). A risk management scope has been published concurrently to initiate discussions with stakeholders on the risk management options being considered. This is of high interest to the personal care industry since driver is some cosmetic products in Canada, such as temporary hair dyes, nail polishes, and body and face makeup (including eye and lip makeup).

Cosmetics Alliance will be reviewing the DSAR and will engage with the CA's committee

In the meantime, if you have any questions or concerns or would like to join our committee please reach out to your CA Regulatory Team.

https://www.cosmeticsalliance.ca/environment-and-climate-change-canada-released-the-draft-screening-assessment-of-2h-1-benzopyran-2-one-7-diethylamino-4-methyl-also-referred-to-as-coumarin-1-on-october-30-it-is-proposed-to-conc/

New Substances Program Information

On November 2, 2020, the New Substances program published the Advisory Note: Animate virus-like particles (VLPs) and sub-viral particles (SVPs) subject to the *New Substances Notification Regulations (Organisms)* on the New Substances program website.

The purpose of this advisory note is to communicate the New Substances program's interpretation of the terms "virus-like particles" (VLPs) and "sub-viral particles"(SVPs) in paragraph (b) of the definition "micro-organism" described in subsection 1(1) of the *New Substances Notification Regulations (Organisms)* [the Regulations]. This regulation applies with Part 6 of the *Canadian Environmental Protection Act, 1999* (the Act), which apply to the manufacture and import of new animate products of biotechnology (living organisms).

## Post-Consumer Waste Updates

### Government releases proposed Blue Box Regulation for comment

The Government of Ontario has posted its proposed Blue Box Regulation under the *Resource Recovery and Circular Economy Act, 2016* for public consultation. When finalized, the regulation will support the transition of Ontario's Blue Box Program to a new framework for waste diversion and resource recovery that makes producers individually accountable and financially responsible for their products and packaging when consumers are finished using them. The

government is seeking feedback on the proposed regulation until December 3, 2020. Learn more.

November 24th, 2020: Consultations on the 2021 Schedule of Contributions

On Tuesday, November 24th, ÉEQ will lead a special consultation, online, in French and English, in anticipation of the approval of the new Schedule of Contributions by the Québec government. During this event, companies have the opportunity to better understand the factors that impact their contribution to curbside recycling in Québec within the framework of an environmental accountability approach in addition to being able to share their comments.

Marie Julie Bégin, Vice-president, Compensation Plan and Isabelle Laflèche, Director, Company Services will present an overview of the context in which the recovery and recycling system is evolving, the rules and adjustments under the 2021 Schedule of Contributions as well as the impacts on upcoming contributions, followed by a question period.

To register for the English session (2PM to 4PM), click here.

To register for the French session (9:30 to 11:30), click here.

Modernizing the Quebec curbside recycling system thanks to the EPR

As part of special consultations on Bill 65, Éco Entreprises Québec (ÉEQ) welcomed the government's decision to place companies at the heart of the curbside recycling system and presented its recommendations to the Commission on Transportation and the Environment last night in order to ensure the success of the modernization of curbside recycling.

The recommendations aim to guarantee that:

1. The principles of extended producer responsibility (EPR) will be respected;
2. Companies will be represented, as soon as possible, by a recognized management organization (RMO);
3. Transition measures between the compensation plan and the modernized curbside recycling system will allow for greater financial predictability;
4. The upcoming regulation will enable companies to assume their responsibilities with the degree of latitude and the flexibility required, in all fairness.

Moreover, ÉEQ will pursue its active participation in collaborative efforts on the modernization of curbside recycling instigated by the government.