Regulatory Essentials – October 28, 2020

Cosmetics Alliance Update

Interactive Training Session - Natural Health Product Site Licensing

Date: Wednesday, October 28, 2020

Time: 2:00 pm - 3:30 pm

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

Learn and Understand:

- Who requires a site licence?
- How to apply for a site licence
- How and when to renew your site licence
- How Health Canada processes applications and renewals

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 Update

Update on Technical Grade Ethanol Authorizations

On October 15, 2020, the Natural and Non-prescription Health Products Directorate updated stakeholder on Technical Grade Ethanol Authorizations. The summary of the call is below.

Hand Sanitizers Containing TGE – October Update EN

Hand Sanitizers Containing TGE – October Update FR

The revised link can be found below:

https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/interim-guide-ethanol-hand-sanitizers.html

Additional packaging and labelling requirements for hand sanitizers - presentation PDF

On October 1st, 2020, NNHPD updated stakeholders on additional packaging and labelling requirements for alcohol-based hand sanitizers packaged in beverage containers policy to help reduce the risk of unintentional ingestion.

Please refer to the PDF below to view the presentation.

Consultation Summary – EN

Consultation Summary – FR

Consultation on Proposed Updates to the Cosmetic Ingredient Hotlist

Late last week, you may have seen that Health Canada (Consumer and Hazardous Products Safety Directorate, CHPSD) initiated their long awaited consultation on proposed amendments to the Cosmetics Ingredient Hotlist. This consultation follows-up on their corresponding Notice to Stakeholders issued in accordance with their standard process in January, 2020 and re-notified in July 2020. Originally scheduled to be published this past Spring, this consultation was delayed due to COVID priorities, and it is only now that CHPSD is in a position to proceed.

The proposals for amendments as published are not a surprise, and certainly reflect the developments we have been developing for quite some time. With this publication, we now have at least a definitive idea of specifically what Health Canada is proposing. Unfortunately, corresponding background and safety signal details remain rather light and illusive. Nonetheless, we are at least now in the position to discuss and review specifics, which will greatly facilitate engagement moving forward.

As you are aware, we have established 2 technical working groups earlier this year to enable and support proactive engagement with a couple of the substance groupings reflected in the original January 2020 Notice to Stakeholders (AHA/PHAs and Retinoids), in addition, we also are expecting a revised proposal regarding eucalyptus oil, based on input/feedback and subsequent reconsiderations from the 2019 proposal, which will require some coordinated follow-up with our friends and colleagues from the US Personal Care Products Council (US PCPC), given past engagement on this specific front. In this regard, work has already been undertaken and continue to be pursued on all of these fronts (as we awaited formal publication of this Consultation Notice).

With this publication, the clock has now officially started – so things are about to get very busy:

We anticipate that the specific proposals regarding the following substance(s)/grouping(s) will likely be of high interest to our membership:

- Alpha/Poly Hydroxy Acids and their Salts (AHA/PHAs) [science task force]
- Retinoic Acid or its Salts or Derivatives [science task force]
- Eucalyptus Oil
- Peroxide and Peroxide-Generating Compounds (oral cosmetics)

Secondarily, of some interest may be the proposals regarding the following:

- P-Hydroxyanisole
- Azelaic acid and its Salts
- Ethylhexyl ethylhexanoate

If you are interested in participating in discussions helping to shape our responses to the AHA/PHA or Retinoic Acid proposals – we will be working these through our corresponding ingredient Science Task Forces. For the remaining proposals, we will be coordinating our engagement jointly within our PCMA/RAIS Committees. Please email regulatory@cosmeticsalliance.ca to join the committee.

Changes to Health Canada Guidance Document - Annex 7 - Stability Reversal

Cosmetics Alliance reached out to Health Canada upon the release of Annex 7 to the Good Manufacturing Practices Guide for drug products – Selected Non-Prescription Drugs on August 26th. The changes to this guidance document were intended to be minor to reflect the amended Food and Drug Regulations for Quarantine and Re-Testing of imported DIN products. Upon review, it was noticed that Interpretation 1 of C.02.027 (Stability) changed from one batch of a product on stability at all times to one batch of a product on stability annually.

After meeting with Health Canada, it was determined that this change was indeed not a minor change and was intentionally changed. CAC pointed out one of the principles of the Self-Care Framework seeks to eliminate differences between NHPs and DINs in the same product category, and hence, this change only exacerbated these differences in the interim.

Health Canada will be re-releasing this guidance document to revert to the original wording for this interpretation.

The 2011 version indicated:

C.02.028

1.2 A minimum of one batch of every strength of the drug is enrolled in the continuing stability program at all times. The principle of bracketing and matrixing deisgns may be applied if justified in accordance with the Health Canada document entitled “Stability Testing of Existing Drug Substances and Products”.

The 2020 version indicated:

C.02.028

Interpretation 3 in GUI-0001 associated with bracketing and matrixing in accordance with ICH for the continuing stability program is replaced with:

3. Enroll a minimum of one batch of every drug strength and container closure system into your continuing stability program each year the drug is produced. Consider packaging size in your choice of batches to be enrolled. You may apply the principle of bracketing and matrixing designs if justified.

This is a very important development for stakeholders as year-end is fast approaching and stability programs for 2021 should be under development. The guidance document will be updated by end of December and CA will notify membership when the updated version is published.

Approach for Site Licence Review – Summary of Teleconference

The Natural and Non-prescription Health Products Directorate (NNHPD) held a teleconference on October 20th on the *approach for Site Licence Reviews*.

Please find below the summary for *Risk-based approach to Site Licenses.*

Risk Based Approach for Site Licences – EN

Risk Based Approach for Site Licences - FR

Environmental Update

Publication of the Final Screening Assessment and the Risk Management Approach for the Triarylmethanes Group

On October 15, 2020 the Chemicals Management Plan released the Final Screening Assessment and the Risk Management Approach for the Triarylmethanes Group. Out of the group of 6 Triarylmethanes substances assessed, of interest is Malachite Green, Basic Violet 4 and Basic Blue 7 as they are used in cosmetics specifically hair dyes. It is concluded that Basic Violet 3, Malachite Green, Basic

Violet 4, and Basic Blue 7 meet the criteria under CEPA as they are entering or may enter the environment that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Malachite Green meets the criteria under CEPA as it is entering or may enter the environment that constitute or may constitute a danger in Canada to human life or health.

We anticipate a consultation on the substances mentioned above used in hair dyes in the upcoming 2021 Hotlist consultation cycle. Please take the time to read the Final Screening Assessment and the Information sheet (attached) and provide us your feedback on possible restriction limits on concentration or exposure/use limits that you want Cosmetics Alliance to explore as means of engaging proactively in the next phase of work. Please provide your feedback as soon as possible.

Post-Consumer Waste Update

Materials from the 2020 Annual Steward Meeting

The Report to Stewards, presentation, webinar recording and Excel file that maps the 2021 fee rates with material categories are available here. The Q&A will be available in the next few weeks.