Regulatory Essentials – May 7, 2019

Cosmetics Alliance Updates

Another Successful Spring Regulatory Workshop

Cosmetics Alliance hosted another successful Spring Regulatory Workshop on May 1 at the Double Tree by Hilton in Montreal. With over 80 attendees, the workshop was found to be a very informative and an enlightening event. Attendees gained valuable insight through important updates provided by CPSD, NNHPD, ROEB, CMP and the Self-Care Products Framework Team.

Stay tuned for all the highlights and photos from the workshop in our next newsletter.

CA's Executive Briefing & Networking Event at Veeva Systems Inc.

June 4, 2019
4:30 to 7:30 pm
Veeva Systems Inc.
20 Toronto Street, Suite 1000
Toronto

Join us for this CA complimentary event intended for leaders or their representatives. Learn about fast moving issues that can affect your business and the opportunities they create.

The Speaker - John Cooper, Director of Strategy, Veeva Claims

The Topic – Navigating the Increasing Complexity of Cosmetics Product Claims

The competitive landscape in the cosmetics category has changed dramatically over the past several years as natural and sustainable trends have taken center stage and a wave of new indie and influencer led brands have rushed to capitalize. These and other factors have added challenges to the already complex task of managing cosmetic product claims. Compounding this is the fact that most companies are using manual, disparate systems for claims management.

Given current trends and the pace of change in cosmetics, it's likely that claims management will get considerably more complex in the not too distant future. Companies without the proper systems and processes in place could be in for a rude awakening.

Hear from product claims management expert John Cooper about how the latest cosmetics trends such as personalization, the rise of influencers, wellness, and accompanying supply chain challenges are merging to further complicate claims management in the cosmetics category. John will also present findings from recent third-party research on claims management challenges, and offer recommendations to help your team prepare for what lies ahead.

Health Updates

Consultation on Proposed Changes to the Cosmetic Ingredient Hotlist

On May 6, Health Canada posted their anticipated proposed updates to the Cosmetic Ingredient Hotlist for consultation (https://www.canada.ca/en/health-canada/programs/consultation-proposed-updates-cosmetic-ingredients-hotlist/document.html).

Proposed Changes:

- **Dihydrocoumarin** – movement from a prohibition to a restriction, limit of 0.035% (leave-on and 3.5% (rinse-off). A review of the available scientific data indicates that the ingredient may cause sensitization at higher concentrations but can be used at low levels without significant risk.
- **Thiurams** – revision to combine many entries into one and also encompass thiuram tetrasulfides which are not presently captured under the Hotlist entry. These substances have all been identified to pose similar skin sensitization risks. Revising the Hotlist entry from a prohibition to a restriction is also being considered because a review of the available scientific data indicates that the ingredients may cause skin sensitization under certain usage conditions but can be used in latex theatrical makeup without significant risk.
- **Eucalyptus Oil** - revision is being considered to better mitigate risk of accidental ingestion, particularly in pediatric populations.
- **Sodium Bromate** – revision to restriction to a prohibition is being considered as sodium bromate is toxicologically equivalent to potassium bromate, which is prohibited. The two entries will be combined into one entry for Bromates.
- **Thioglycolic acid and its salts** – revision is being considered due to changes in ingredient usage. New conditions regarding hair products and products for use in the area of the eye will be considered.
- **Miscellaneous revisions** – several entries will be revised to include new synonyms and CAS number or make minor corrections.

This consultation closes on July 1, 2019. Cosmetics Alliance will be working with our Risk Assessment and Ingredient Safety Committee to develop and submit comments. If your company is not represented on this Committee and has any feedback on the proposed changes, please contact your CA Regulatory Team.

<u>Changes at the Regulatory, Operations and Enforcement Branch</u>

Tina Green, Assistant Deputy Minister, has moved to the Treasury Board of Canada Secretariat. Please note Stefania Trombetti will be the Acting Assistant Deputy Minister and Lindsay Hoillett and Kimby Barton will be the Acting Director General at the Regulatory, Operations and Enforcement Branch (ROEB).

<u>NHP MAP Presentation and Client Services Update</u>

The Natural and Non-prescription Health Products Directorate (NNHPD) held a teleconference call on April 10, 2018 with industry associations. The purpose of this phone call was to provide a heads up on the imminent publication of the Natural Health Products Management of Applications Policy (NHP MAP) and an update on the work done to improve Client Services since the teleconference held on December 14, 2018.

Recap of December teleconference:

During the December call, NNHPD presented changes it was considering to help improve the predictability of its client services.

•Turning off the client services phone line;

•Making greater use of the auto-reply function to address requests for an update on the status of an application; and

•Extending the performance standard to respond to client inquiries submitted to the generic email account.

Ways in which NNHPD could proactively share common Questions and Answers was discussed. Following the call, associations were sent an email, which provided a summary of the phone call and confirmed which changes would be made at that time.

Action taken since December:

Since the December call, NNHPD has taken the following measures:

•Implemented two changes discussed during the December call: turning off the phone line, and making use of the auto-reply function to address requests for a status update. The latter of which resulted in an update to the client service auto-reply.

•Developed Q&As for three of the most frequently asked questions.

•Carried out blitzes to bring down the backlog of inquiries.

•Reviewed the resources assigned to the client services function and added a more senior staff to take on the role of triaging the incoming email inquiries with the objective of improving the efficiency and effectiveness of that function.

•Identified a short list of 'frequent' inquirers and have started proactively engaging with them to understand what is driving the large number of inquiries and solicit suggestions for improving the client services.

Current State of Client Services:

During last fiscal year (April 2018-March 2019), NNHPD received over 12,000 email inquiries, with an average of approximately 1,100 inquiries per month. Furthermore, since December 2018, there has been a continued increase in the number of requests for an update on the status of an application, with a peak of 277 such inquiries received in February 2019. Of the inquiries received since December, none have been responded to within the current 10-business day performance standard. Other than a few exceptions, NNHPD has closed off all inquiries received in 2018 and, those few remaining, have been prioritized and are being closely monitored.

Follow-up from April 10 teleconference:

During the April 10 teleconference, additional measures that NNHPD is considering, including extending the performance standard for client inquiries and the approach to prioritizing incoming inquiries was discussed. NNHPD solicited suggestions from associations on improving the client service and discussed the sharing of best practices when submitting an inquiry. Following the teleconference, NNHPD has actioned or will be taking action as follows:

•NNHPD updated the client service auto-reply (attached herein) to include:

- Reference to the updated NHP MAP;
- Tips for interacting with client services; and
- Guidance on submitting inquiries related to technical or system issues.

• NNHPD has provided, as an attachment to this message, the Q&As for the most frequently asked questions. NNHPD is exploring ways to incorporate them into the client service auto-reply.

•NNHPD is considering your feedback on a change to the current performance standard of 10-business days for client services.

•NNHPD will schedule another teleconference call with associations in June 2019 to touch base on the progress made in light of the improvements implemented to the client services function.

Associations were requested to carry-out the following actions:

•Associations to share this message and its attachments with their members.

•Associations to provide feedback on the approach to prioritizing or triaging inquiries.

•Associations to provide suggestions to help improve the clarity of the auto-reply and the Q&As, and recommend additional Q&As for development.

CA is accepting comments or suggestions on the approach until May 27, 2019. You can also provide comments directly to Stephanie Reid at Stephanie.reid@canada.ca.

Auto Reply

Product Classifications

Application Steps

Status Update

Removal of Single Ingredient Vitamin and Mineral Monographs and Publication of Revised Bundle 8 Monographs to Address "Statements to the effect of"

The Natural and Non-prescription Health Products Directorate (NNHPD) has removed the following single ingredient monographs from the Listing of Monographs:

1. Beta-Carotene
2. Biotin
3. Calcium
4. Chromium (from chromium Picolinate)
5. Chromium (from non-picolinate sources)
6. Copper
7. Folate
8. Iodine
9. Iron
10. Magnesium
11. Niacin
12. Niacinamide
13. Pantothenic Acid
14. Riboflavin
15. Selenium
16. Thiamine
17. Vitamin A
18. Vitamin B12

19. Vitamin B6
20. Vitamin C
21. Vitamin D
22. Vitamin E (from rac-alpha-tocopherol and esters)
23. Vitamin E (from RRR-alpha-tocopherol and esters)
24. Zinc (from non-picolinate sources)
25. Zinc (from Zinc picolinate)

From this point forward, applicants submitting applications for single ingredient vitamin or mineral products may attest to the Multi-Vitamin/Mineral Supplements monograph that outlines the parameters for the use of vitamins and minerals. The NNHPD does not require notification from the company of this attestation change.

Please note that product licence holders are expected to revise products affected by the Multi-Vitamin/Mineral Supplements monograph revisions as outlined in the Natural Health Products Management of Applications Policy. Licence holders are excepted to submit an amendment or notification for affected products, to ensure that the product aligns with the most up-to-date version of the monograph. The NNHPD encourages companies to use the Amendment and Notification form.

All new submissions are expected to be in line with the most current version on the monograph.

The Natural and Non-prescription Health Products Directorate (NNHPD) updated the following monographs to reflect the changes to the "Statements to the Effect of":

1. Amylase, alpha-
2. Cellulase
3. Chymotrypsin
4. Counterirritants
5. Galactosidase, alpha-
6. Lactase
7. Lipase
8. Medicated vapours
9. Pancreatic Enzymes
10. Papain
11. Protease, Fungal
12. Trypsin

Please visit What's New Page to find a listing of modifications to the Natural Health Products Ingredients Database (NHPID) since the last update.

DEL Bulletin LEPP No. 54 – Survey on Canadian Drug Exportation

Health Canada invites you to participate in a survey to assess the impact of proposed regulatory amendments to stakeholders.

In its Forward Regulatory Plan for 2019-2021, Health Canada included the proposal *Modernizing Drug and Medical Device Establishment Licensing Frameworks – Amendments to the Food and Drug Regulations and Medical Devices Regulations*.

As part of the regulatory development process, Health Canada is undertaking a Cost-Benefit Analysis (CBA) to understand the impact that the proposed changes may have on regulated parties. Information collected through the attached survey will provide a better understanding of the Canadian drug and device exportation landscape, and consequently inform the development of an effective, transparent and consistent CBA. This survey will help Health Canada assess the potential administrative and compliance costs of the proposed regulatory amendments on industry, as well as allow stakeholders to submit comments and obtain answers to any questions they may have.

The survey is available in English and French. Please submit your responses by June 24, 2019 via email at hc.cpls-pcal-consultations.sc@canada.ca; by fax at 613 -941-7360 or by mail to the address:

Policy and Regulatory Strategies Directorate
Regulatory Operations and Enforcement Branch
Health Canada
Mail Stop 1907,
7th floor, Jeanne Mance Building
200 Eglantine Driveway, Tunney's Pasture, Ottawa, Ontario K1A 0K9

Release of Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs)

The above referenced guidance document was released by Health Canada and is posted on the website.

This guidance document provides assistance on the interpretation of the regulatory requirements associated with a DIN. It provides guidance to manufacturers on their obligation to accurately report to Health Canada the following notifications for a change of drug status within the required timelines: Market notification, 12 months without sale notification, Discontinuation of sales notification.

The document is finalized and effective.

The document is a consolidation of and replaces the following documents:

- Guidance Document: Cancellation of a Drug Identification Number (DIN) and Notification of Discontinuation of Sales
- Issuance of Drug Identification Numbers for New Drugs
- Notice: Instructions for filing Drug Notification Forms (DNF) and Supporting Documents Provided in Electronic Format
- Assignment of Drug Identification Numbers (DINs) According to Product Name
- Notice – Revision of the Procedure on the issuance of Drug Identification Numbers (DINs) for Unit Dosage Pre-filled Syringes
- ARCHIVED - Drug Identification Number: A Brand Name Product with Different Fragrances, Flavours or Colours

Environmental Updates

Looking to Shape Scientific Assessment – Addressing Talc Safety under the Chemicals Management Program

On April 24, 2019, Cosmetic Alliance Canada, in collaboration with the Industrial Minerals Association North America (IMA-NA) representing the major suppliers of cosmetic-grade talc facilitated a meeting with Health Canada science officials to review and elaborate on the extensive input that industry collectively submitted regarding the Draft Screening Assessment Report (DSAR) published this past December. Armed with input and insights from our Talc Science Task Force and IMA-NA's Science Working Group, CA Canada's Beta Montemayor led a delegation of subject matter experts: Mr. Glen Murphy and Dr. Susan Nicholson (J&J); Mr. Matthew Dent and Mr. Anthony Bowden (Unilever); Dr. Julie Goodman (Gradient Consulting); Dr. Paul DeLeo (Integral Consulting); and Mr. Mark Ellis and Ms. Anne McConnell (IMA-NA) in presenting our collective critical commentary in response to the published DSAR. This scientific dialogue is a paramount follow-up step in looking to ensure that Health Canada consider significant reforms in their overall assessment to allow for a more appropriate reflection of the weight of available evidence that would ultimately hold up to scientific scrutiny.

Despite the critical nature of our commentary, HC officials were appreciative of this opportunity to review in detail our technical commentary. Overall, the meeting was very productive with tangible next steps and outcomes for further follow-up that will help shape HC's continued review and possible revisions to the DSAR moving forward. We look forward to on-going stakeholder engagement in this regard and will continue to develop and pursue our continued technical engagement on this file through our Talc Science Task Force and Risk Assessment and Ingredient Safety Committee.

If you have any questions regarding these activities or would like to discuss how to get involved in this ingredient defense strategy, please do not hesitate to get in touch with your CA regulatory team (regulatory@cosmeticsalliance.ca).

We would like to recognize and thank the CA Canada Talc Science Task Force and the member company experts (above) for their contributions in supporting these defense efforts on behalf of CA Canada and the cosmetic/personal care industry.

Repeal the Toxics Reduction Act, 2009 and All Associated Regulations by December 31, 2021

The Ontario Ministry of the Environment has announced that it is repealing the Ontario Toxics Reduction Act, 2009, coming into force December 31, 2021. The repeal is intended to reduce burden associated with the overlap between Ontario's toxic reduction planning and the federal government's Chemicals Management Plan. This concern was specifically made by CA (then CCTFA) in the consultation conducted by the former Ontario Government when the bill was first introduced. Also, the program did not achieve any meaningful reductions of substances (i.e. an overall reduction of only 0.04% of substances used, created and released from regulated facilities was achieved).

What this means is that facilities will have to maintain reporting obligations until December 31, 2021, including annual reporting of substances meeting reporting thresholds and corresponding progress reports. After 2021, these obligations will be dropped – with facilities continuing to be required to meet the federal National Pollutant Release Inventory (NPRI) reporting for releases of reportable substances to air, land and water.

This action follows public consultations regarding the proposed repeal, whereby Government received a wide range of comments from interested parties (over 400+ comments received) including input from public, industry, municipalities, and NGOs. Comments were mixed and included:

- Support for proposed repeal on the basis of duplication and lack of commensurate benefit
- Concerns with deference to federal program and apparent focus on cutting red tape or favoring interests
- Right to know about toxic substances in the community (despite observations with duplication with federal programs)
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Through our involvement with the Canadian Manufacturing Coalition, Cosmetics Alliance was specifically consulted by the Ontario government for our expertise on the federal CMP. CA had the opportunity to contribute our perspective regarding chemical management and the need to avoid unnecessary regulatory duplication. As such, we are most pleased with this announcement.

If you have any questions, please don't hesitate to contact your Regulatory Team.

Webinar – Awareness of the Environmental Emergency Regulations, 2019

Environment and Climate Change Canada will be hosting webinar in order to provide awareness of the *Environmental Emergency Regulations, 2019* (E2 Regulations, 2019). The webinars will be held in both official languages on separate dates. The same webinar material will be presented on three different dates, so attendees only need to attend one webinar date. The English webinars will be held on May 7, June 4 and July 9. The recording of the webinar and related material will be shared following the last scheduled webinar. To access the webinar of your choice, please go to https://gts-ee.webex.com/gtsee/onstage/g.php?PRID=5a035421f1b8b7e37703103350f3cc08.

Background: The official publication of the E2 Regulations, 2019 in the Canada Gazette, Part II, was on March 6, 2019. The E2 Regulations, 2019 will come into force on August 24, 2019. Until then, the previous regulations, i.e. the Environmental Emergency Regulations, are in force.

The E2 Regulations, 2019 apply to the owner or the person in charge, management or control of a substance listed in schedule 1 of the regulations. When specific quantity or container capacity thresholds are met or exceeded, this person must notify Environment and Climate Change Canada and submit information on the installation and substance concerned. When both the quantity and container capacity reach or exceed the thresholds, the responsible person must prepare, bring into force and periodically exercise an environmental emergency plan (E2 plan).

The E2 Regulations, 2019 add 33 substances to the list of regulated substances. They clarify and strengthen requirements for emergency planning and public notification before, during and after an environmental emergency. The regulations introduce obligations to report periodically on facilities, substances, and E2 plans, as well as to activate the E2 plan in the case of an emergency.

For more information related to the Environmental Emergency Program, please visit Environment and Climate Change Canada's Web site

at https://www.canada.ca/en/environment-climate-change/services/environmental-emergencies-program.html

Final Screening Assessment for Epoxy Resins Group

The final screening assessment for Epoxy Resins Group was published on May 4, 2019. It was concluded that the Epoxy Resin Group does not meet any of the criteria set in Section 64 of CEPA. Below is the list of the Epoxy Resins Group that were part of the Final Screening Assessment.

CASRN	Common Name	DSL Name
25036-25-3	DGEBA epoxy resin	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[oxirane]
25068-38-6	DGEBA epoxy resin	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane
25085-99-8	DGEBA epoxy resin	Oxirane, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis-, homopolymer
28064-14-4	Novolac epoxy resin	Phenol, polymer with formaldehyde, glycidyl ether

Other Update

Ad Standards Staff Update

Ad Standards would like to announce the retirement of Janet Feasby, VP, Standards and Nicole Bellam, VP, Clearance Services. Ad Standards is incredibly grateful for their combined contributions over the past 20 and 17 years (respectively) and wish them nothing but the best in their next chapters. Janet will remain with Ad Standards until May 31, 2019, and Nicole will remain until June 30, 2019; both will remain on retainer for the foreseeable future thereafter.

Ad Standards is pleased to announce the appointment of Catherine Bate to the position of Chief Legal & Policy Officer, effective April 29, 2019. Catherine is a renowned leader in the field of marketing, advertising and consumer product regulatory law in Canada. Previously a Partner with Miller Thompson LLP, Catherine's practice encompassed issues ranging from consumer marketing strategies, promotions and sweepstakes, and data privacy practices. She also advised clients on consumer protection matters and assisted with product claims, labelling compliance, and navigating the rules around specially regulated products.

Please welcome Catherine to Ad Standards! She can be reached at catherine.bate@adstandards.ca