Regulatory Essentials – August 8, 2018

Cosmetics Alliance Updates

Register for Cosmetics Alliance Fall Regulatory Workshop

While Summer might almost be over, Fall is definitely something to look forwards too as Cosmetics Alliance will be hosting their annual Fall Regulatory Workshop. This year's Fall Regulatory Workshop will be on:

Date: Wednesday, October 10, 2018
Registration: 8:15 a.m. - 9:00 a.m.
Workshop: 9:00 a.m. - 4:30 p.m.
Location: The Omni King Edward Hotel, Toronto

Cosmetics Alliance Regulatory Workshops provide members with the opportunity to stay up-to-date and informed on "everything regulatory". You won't want to miss this opportunity to hear from government officials, industry experts and Cosmetics Alliance staff first hand on issues that will directly affect your business.

Register before Monday, September 10 to take advantage of early bird pricing. Receive discounted pricing when you send more than one representative from your company.

To Register: https://www.regonline.ca/registration/Checkin.aspx?EventID=2527886

Health Updates

Good Pharmacovigilance Pilot Project

Health Canada is reviewing the GVP inspection process with the intent to modernize it and create efficiencies. As part of that review, Health Canada is considering oversight of foreign MAHs to better align with international standards. To that end a pilot of two different inspection approaches will be launched in order to verify the compliance of foreign MAHs. The two approaches include:

- Performing an off-site paper assessment for low risk establishments (for example over-the-counter (OTC) drug products):

- The off-site assessment will be similar to the current on-site inspection process; however, documents/records will be reviewed from the Health Canada office. Correspondence with the foreign MAH, including requests for documents, will be performed via email or phone.

- Conducting an on-site inspection of the foreign MAHs at the location of a Canadian importer for medium to high risk establishments (for example, prescription drugs):

- The on-site inspection of the foreign MAH will be performed at the location of a Canadian importer/representative. The foreign MAH will need to be available, in-person or remotely, to address the inspector's questions as the foreign MAH is the inspected party.

A number of establishments will be selected to take part in the pilot, which is set to begin in June 2018 and is expected to last up to 12 months. Selected foreign MAHs and importers will be informed of their anticipated participation in the coming weeks. The experience and

information gathered during the pilot will be used to assess the inspection model for foreign MAHs. After the evaluation of the foreign MAH inspection model, your establishment will be notified of the outcome of the pilot. Health Canada posts results of GVP inspections and will post inspections covered under the pilot. *Preparing and Submitting Summary Reports for Marketed Drugs and Natural Health Products - Guidance Document for Industry*

Once your establishment has been selected for inspection over the next 12 months, Health Canada will provide a Questionnaire to Complete and a final list of Drug Products Marketed in Canada. Please see below for inspection logistics.

Inspection Logistics:

a) Availability of pharmacovigilance personnel

The Inspection will be conducted off-site (e.g., by phone and email from the inspector's office). We require that personnel involved in pharmacovigilance activities be readily available to respond to requests, including:

- Responding to questions,
- Providing requested documents in English or French,
- Providing access to the systems and/or databases used to conduct pharmacovigilance activities.

These inspections can be conducted in English or in French. Please confirm the language of your choice in the questionnaire.

b) Role of the importer

Please note that the inspector may need to communicate with the Canadian importer(s) of your product(s). The Canadian importer is responsible for certain pharmacovigilance activities such as collection of adverse drug reaction (ADR) reports since their name is on the label of the Canadian product. Furthermore, the inspector may inform importers of any deficiencies found during the inspection. Please let us know if you have any objection or confidentiality concerns regarding our communication with the importer.

If you have one or multiple Canadian importers, please identify where you would like the inspection to take place. You will be responsible for discussing common scheduling and availability with the importer.

c) Pharmacovigilance (PV) Activities

Please inform us of the organisation of your PV activities in regards to the product(s) marketed in Canada.

Once the responses are compiled for the questionnaire, if your establishment is selected an inspector of Health Canada will communicate with the designated person by email or phone to schedule the inspection.

If you have any questions regarding the Pilot Project please reach out to your CA Regulatory Team.

Consultation on the Mandatory Reporting Under Vanessa's Law

Health Canada is proposing to amend the Food and Drugs Act on Serious Adverse Drug Reaction Reporting — Hospitals and the Medical Devices Regulations (Medical Device Incident Reporting — Hospitals). The proposed regulation would amend the Food and Drug Regulations and the Medical Device Regulation to require hospitals to report SADR- and MDI-related information directly to Health Canada. The collection and assessment of this real-world information will help Health Canada to better monitor the safety of therapeutic products once they are on the Canadian market. The central objective of the proposed regulations is to improve the quality and increase the quantity of SADR and MDI reports, and to expand on the real world evidence used by Health Canada to monitor the safety and effectiveness of therapeutic products, as part of a life-cycle approach to the regulation of such products. For information on the timeline for reporting, benefits of the proposed regulation and required information for reporting please visit Canada Gazette Part II.

Webinar on CCPSA General Prohibition

The Consumer Product Safety Program of Health Canada wishes to introduce a new approach to communicate with stakeholders about its compliance and enforcement activities under the General Prohibition provisions of the *Canada Consumer Product Safety Act* (CCPSA). At the webinar, CCPSA will be seeking your comments on this proposed approach and outline the benefits of this approach along with industry's responsibilities.

General Prohibition*: As set out in sections 7(a) and 8(a) of the CCPSA, General Prohibition, broadly speaking, prohibits anyone from manufacturing, importing, advertising or selling a product in Canada that poses a danger to human health or safety. It applies to all consumer products and is fundamental to the purpose of the CCPSA, which is to protect the public by preventing and addressing dangers to human health or safety posed by consumer products in Canada.*

Industry and associations are invited to participate in this consultation.

English session: Friday, August 17, 2018 at 1:00 pm **(EDT) Eastern Daylight Time**

French session: Monday, August 20, 2018 at 1:00 pm **(EDT) Eastern Daylight Time**

To register, please e-mail hc.ccpsa-lcspc.sc@canada.ca and indicate which session (French or English) you would like to attend.

Registration will take place on a first come, first serve basis.

Notice of Intent to Amend Prescription Drug List

The purpose of this Notice of Intent to Amend the prescription Drug List is to announce that Health Canada will add phytocannabinoids to the Human and Veterinary Prescription Drug Lists (PDL). This addition will be effective upon the coming into force of the Cannabis Act.

The listing will read:

Drugs containing any of the following:	Including (but not limited to)	Qualifier	Effective Date (yyyy-mm-dd)
Phytocannabinoids produced by, or found in, the cannabis plant and substances that are duplicates of such phytocannabinoids.		except: 1. derivatives of cannabis as defined in subsection 2(1) of the Cannabis Act that are exempt from the application of the Cannabis Act under the Industrial Hemp Regulations and that do not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid, or 2. anything referred to in Schedule 2 to the Cannabis Act that contains no more than 10 µg/g delta-9-tetrahydrocannabinol and that does not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid.	Upon the coming into force of the Cannabis Act and Regulations.

Rationale:

Clinical evidence supporting the safety and efficacy of cannabis and its constituents for therapeutic purposes is currently insufficient to set acceptable dosage or other thresholds for non-prescription use. While Health Canada has previously authorized health products containing cannabis, there remains significant scientific uncertainty regarding the pharmacological actions, therapeutic effectiveness and safety of the majority of phytocannabinoids. The cannabis-based drug products which have been authorized by Health Canada have been studied, authorized and used in specific conditions. While these authorized products have contributed to the global body of knowledge concerning the safety and efficacy of cannabis-based therapies, the presence of scientific uncertainty and limited market experience gives rise to the need for a precautionary approach. Listing all phytocannabinoids on the PDL addresses this uncertainty by allowing healthcare practitioners to monitor and manage any unanticipated effects.

When added, all phytocannabinoids will remain listed on the PDL until there is sufficient scientific evidence (e.g., as demonstrated through a submission to Health Canada) to change the prescription status of a particular phytocannabinoid when used in specific conditions. Pursuant to section C.01.040.3 of the Food and Drug Regulations, Health Canada considers several criteria when deciding whether a health product would be required to be sold as a prescription drug. Additional information on how Health Canada determines prescription status (or non-prescription status) is available in the Guidance Document: Determining Prescription Status for Human and Veterinary Drugs.

Cannabis Regulation Published in Canada Gazette, Part II

The *Cannabis Regulations,* which outline the rules for the legal production, distribution, and sale of cannabis, were published yesterday, July 11th 2018, in Canada Gazette II.

Guidance on the regulatory framework for health products containing cannabis or for use with cannabis that are approved under the *Food and Drugs Act* (FDA) is now available. This guidance document provides information on requirements for licensed activities, rules that apply to the health products themselves, and obligations for certain healthcare professionals.

For questions related to submissions and applications for health products containing cannabis or for use with cannabis, natural health products containing permitted parts of the cannabis plant, or clinical trial requirements, please contact the cannabis single-window at the Health Products and Food Branch of Health Canada: hc.hpfb_cannabis_dgpsa.sc@canada.ca

Environmental Updates

Final Screening Assessment for Phenacetin

On July 28, 2018 the Final Screening Assessment for Phenacetin was posted to the Canada Gazette Part II. It is concluded that phenacetin does not meet any of the criteria set out in Section 64 of CEPA. Since phenacetin is listed on the *Domestic Substances List* (DSL), its import and manufacture in Canada are not subject to notification under the *New Substances Notification Regulations (Chemicals and Polymers)*. However, since phenacetin is considered to have human health effects of concern, there is suspicion that new activities that have not been identified or assessed could lead to this substance meeting the criteria set out in CEPA. Therefore, the Government of Canada intends to amend the DSL to indicate that the significant new activity (SNAc) provisions under subsection 81(3) of the Act apply with respect to this substance.

Publication of the Draft CMP Screening Assessment and Risk Management Scoping Document for Benzophenone

******* IF YOU MANUFACTURE NAIL POLISH OR NAIL CARE PRODUCTS – PLEASE REVIEW THIS MEMBER UPDATE *******

This past weekend (August 4, 2018), Environment and Climate Change Canada (ECCC) and Health Canada (HC) published their **DRAFT SCREENING ASSESSMENT REPORT** (DSAR) and **RISK MANAGEMENT SCOPING DOCUMENT** (RM Scope) for BENZOPHENONE (CASRN: 119-61-9). We have also taken the liberty to attach the corresponding Public Information Summary that was published in conjunction with these documents.

PROPOSED CONCLUSIONS:

The draft assessment concludes that benzophenone be proposed to be **'CEPA-Toxic'** on the basis of concerns that it may present a potential **human health risk**. The assessment affirms that benzophenone as a potential CMR substance (based on evidence that benzophenone is carcinogenic in rodent models) and outlines critical concerns with potential renal toxicity from a non-cancer perspective. These conclusions are consistent with the recent scientific scrutiny of this substance both domestically and abroad. On this basis, these conclusions are not surprising.

Although benzophenone occurs naturally and is used in a wide variety of applications, this draft assessment isolates concerns with only two specific use scenarios – use in cosmetics and use in paints and coatings. In both these use scenarios, a comparison of worst-case estimates of exposure associated with **nail polish** and interior paint with critical effect levels of concern are demonstrated to result in margins of safety that are inadequately protective.

The assessment also concludes that benzophenone does NOT present a risk to the environment nor is it entering the environment in quantities that pose a risk to ecological health.

NOTE: *This is only a DRAFT assessment and as such, these proposed conclusions are subject to further consultation (see below). On this basis, it is early in the CMP publication process, and there will be significant opportunity for follow-up and scientific engagement, moving forward*.

PROPOSED RISK MANAGEMENT:

On this basis, it is proposed that risk mitigation measures addressing both of these use patterns be considered. Specific to the nail polish use, Health Canada will consider the following risk management options:

- Designation of an appropriate **RESTRICTION** via addition to the Canadian Cosmetics Ingredient Hotlist [note: the attached synopsis and information sheet is generic and simply reports consideration of addition of benzophenone to the "Hotlist'; Cosmetics Alliance was notified by HC that the intent at this time is to limit their action to a product restriction, rather than an outright prohibition]

- Designation of a Significant New Activity Notice (SNAc) for 'new' uses/activity in cosmetics that would require information to be submitted prior to such new uses/activities to enable an assessment as to whether or not they would need to be managed, accordingly

- Specific risk management details will be finalized following publication of the Final Screening Assessment (scheduled for late Q1 2019), assuming these proposed conclusions are maintained, following consultation.

IMPLICATIONS:

The focus of any corresponding risk management activities from a cosmetic perspective will be on the use of this substance in **NAIL POLISH**. Consequently, the impact of these publications should only implicate those members that manufacture/import nail polishes containing benzophenone.

Furthermore, the scope of this assessment is specific to benzophenone as a discrete substance (CASRN: 119-61-9) and does not extend or apply to other benzophenone derivatives. This is important as it would NOT be appropriate to extend these conclusions in any way to other benzophenone derivatives that may be of interest from a cosmetic/personal care perspective.

NEXT STEPS:

- Following official publication of these documents this weekend, Cosmetics Alliance will be issuing a member brief (issue update) summarizing these developments. A courtesy copy of this update will be shared with the Allied Beauty Association (ABA), the Direct Sellers Association (DSA), Food and Consumer Products of Canada (FCPC) and the US Personal Care Products Council (PCPC)
- We will also update our international trade association partners of these developments, indicating the very limited scope of these publications
- Monitor corresponding developments for possibilities of expansion in scope of coverage to other derivatives

FOR NAIL POLISH SPONSORS THAT MAY BE DIRECTLY IMPACTED:

- Cosmetics Alliance will undertake a detailed science review to investigate the possibilities of further engagement on the risk assessment
- In the interim, if you have any questions or concerns with the proposed risk assessment, please share your thoughts with your Cosmetics Alliance Team
- These publications are subject to a 60-Day formal comment period which will come due October 2, 2018. Pending the outcomes of our internal review and input from our members, Cosmetics Alliance will consolidate feedback for submission, as appropriate

Note: Given the now confirmed limited scope of these publications, Cosmetics Alliance will not be producing any proactive, external communication materials regarding these pending publications.

Please do not hesitate to your Cosmetics Alliance Team if you have any questions or would like to discuss these new developments in further detail.

Chemicals Management Plan Progress Report

The tenth issue of the CMP Progress Report was posted on the CMP website on July 31, 2018. The CMP Progress Report includes highlights on Substance Assessment Progress, Risk Assessment and Risk Management Highlights, Prioritization Results for the Revised In-Commerce List Etc. Please review the CMP Progress Report and let your CA Regulatory Team know if you have any questions.

Post-Consumer Waste Updates

Recycle BC – Consultation on Program Plan Phase II

The Q&As from Recycle BC's recent Program Plan Phase II consultation meetings are now available on the Recycle BC website. If you were not able to attend a consultation meeting in-person or via webinar, a recording of the meeting and the presentation deck, are also

available. Recycle BC needs your feedback on the updated Program Plan by Thursday, September 6, 2018. Please submit feedback and questions via email to consultation@recyclebc.ca.