

Regulatory Essentials – January 23, 2019

Cosmetics Alliance Update

The Value of Membership – 2018 Highlights and Membership Renewal 2019

We need your involvement and commitment in order to help Cosmetics Alliance Canada advance the collective interests of the cosmetics and personal care products industry.

Please click [here](#) for CA's 2018 highlights with information about the Association's benefits and services, advocacy efforts, and the value of membership to you and your business.

Click here for the [steps](#) to renew.

Cosmetics Alliance Attends NNHPD's Multi-Lateral Meeting in Ottawa

On January 18, 2019, Cosmetics Alliance attended Natural and Non-prescription Health Products Directorate's (NNHPD) Multi-Lateral Meeting in Ottawa. Beta Montemayor and Richards Parcels from Cosmetics Alliance along with CA's Product Compliance and Market Access (PCMA) Committee Vice-Chair, Francois Roberge represented CA at this session. Key topics that were discussed include

- NHP Management of Applications Policy
- Plain Language Labelling and Monographs
- Summary Safety Review for Sunscreen Products
- Self-Care Framework

CA will be scheduling a debrief with its PCMA and Facility Compliance and Manufacturing (FCM) Committees in the coming weeks. Once we receive the materials from the meeting we will notify you.

Health Updates

Plain Language Labelling Implementation Update on Existing Products

As many of you are aware all drug products on the market must be compliant with PLL by June 30, 2021. CA would like to highlight that NNHPD does not require sponsors to make another PLL submission to re-align with the labelling flexibilities that are currently available on the market. If a product was approved (or otherwise deemed PLL compliant) using the Tailored Flexibilities for Category IV products, there is no requirement to make another submission. Instead, upon the next submission for that product, the labels of the product shall be revised to align with the PLL guidance that is current at that time.

Sponsors of existing products seeking to align with the PLL Regulations do not need to file a submission if they use the Labelling for Low Risk Non-prescription Drugs flexibilities listed in Table 5 of the [Guidance Document: Labelling Requirements for Non-prescription Drugs](#) and there are no substantive changes to the label that would otherwise trigger the issuance of a DIN or NOL.

NHP Product License Applications

Recently, CA became aware that when attempting to complete web-based PLA compendial application for Primary and Secondary Sunscreen products containing nano Titanium dioxide and Zinc oxide, applicants are unable to proceed with the application. NNHPD is currently working on resolving the issue and we will let you know once it is resolved. In the meantime, applicants are requested to use the current version of the e-PLA.

Outstanding responses for products Containing Green Tea Extract (GTE) as a Medicinal Ingredient

This is to advise you that on the week of January 21st, 2019, NNHPD may be reaching out to license holders who have not yet responded to the notice to impacted stakeholders that was issued on November 14th, 2017. This notice served to inform impacted stakeholders that a Summary Safety Review (SSR) was published by the Marketed Health Products Directorate (MHPD) and revealed a risk of liver injury associated with NHPs containing GTE. In this notice, the NNHPD requested changes to licenses and labels for all products containing GTE as a MI. In addition to specifying a subpopulation of 18 years of age or older, the following risk information had been revised [new text bolded]:

- ▶ Enhancement of the current cautionary risk statement to the following:
 - “If you have a liver disorder, consult a healthcare practitioner prior to use. **Stop use if you** develop symptoms of liver trouble **such as yellowing of the skin/eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite and consult a healthcare practitioner**”
- ▶ Addition of the following risk information:
 - **“Rare, unpredictable cases of liver injury associated with green tea extract-containing products have been reported (in Canada and internationally)”**

Impacted stakeholders were given one year to comply with NNHPD’s request (i.e., by November 14, 2018). While reminder notices were issued to non-responding licence holders on May 14, 2018, June 14, 2018, September 14, 2018 and October 15, 2018, a number of responses remain outstanding. As a result, the NNHPD will be issuing section 16 notices (request for safety information) to the non-responding licence holders. In the notice, licence holders will be given 15 days to respond. Failure to respond within the prescribed timeframe will result in the issuance of a section 17 notice (direction to stop sale). Issuance of these notices will be on a biweekly basis and will continue until June 2019.

Should you have any questions or concerns regarding this notice, please feel free to contact the NNHPD’s Risk Management Division by email at hc.rmd.coordination_dgr.sc@canada.ca.

Health Canada Launches Healthy Homes Campaign

Health Canada has recently launched the [Healthy Home Social Marketing Campaign](#) as a key part of CMP outreach initiative led by Health Canada. This Social Marketing Campaign stemmed from the Recent Stakeholder Advisory Council meetings and the campaign preview at the November Multi-stakeholder Workshop. The objective of Healthy Home is to raise awareness among Canadians about the health risks from chemicals and pollutants that might be in and around their home and to encourage Canadians to take measures to make their home and families safer and healthier. Healthy home is an important response to what was heard from SAC members about ways to strengthen CMP public outreach. The purpose of the campaign is

to have a one-stop shop approach that information on chemicals and other pollutants is accessible in one place, easier to understand and tailored to Canadians needs at the household level. The site contains [Household Chemical Safety](#) page which outlines buying, using, storing, disposing chemicals and briefly outlines the hazards symbols commonly found on household chemicals. There is also a link to "[Look up Chemicals and Pollutants](#)" which contains a list of 24 chemicals with a description of what they are and where they can be found. Important chemicals on that list to the personal care products industry are:

- Benzophenone
- Coal Tars
- Petrolatum
- Phthalates
- Selenium
- Solvent Violet 13
- Talc
- Triclosan

Please take the time to review this campaign and let your CA Regulatory Team know if you have any concerns.

Environmental Updates

Draft Screening Assessment of Six Substances in the Pigments and Dyes Group

The Government of Canada released [the Draft Screening Assessment \(DSA\)](#) of six substances in the Pigments and Dyes Group on the DSL on January 5, 2019. The DSA is open for a 60-day consultation period with the anticipated publication of the final screening assessment for March 2020. Twenty-five substances are referenced in the Chemicals Management Plan as part of the [Pigments and Dyes Group](#). Six out of the 25 were assessed as they met the categorization criteria of CEPA and were considered a priority based on other human health concerns. Below is the list of the six substances assessed.

Substances in the Pigments and Dyes Group		
CAS RN	Domestic Substances List name	Common name
596-03-2	Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 4',5'-dibromo-3',6'-dihydroxy-	D&C Orange 5
1326-03-0 a	Xanthylum, 9-(2-carboxyphenyl)-3,6-bis(diethylamino)-, molybdatetungstatephosphate	Pigment Violet 1
8005-03-6 a , b	C.I. Acid Black 2	Acid Black 2
12224-98-5 a	Xanthylum, 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethyl-, molybdatetungstatephosphate	Pigment Red 81
26694-69-9	Xanthylum, 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethyl-, ethyl sulfate	NA
42373-04-6	Thiazolium, 3-methyl-2-[(1-methyl-2-phenyl-1H-indol-3-yl)azo]-, chloride	Basic Red 29

It is proposed that D&C Orange 5, Pigment Violet 1, Acid Black 2, Pigment Red 81 (CASRN 26694-69-9) and Basic Red 29 do not meet the criteria set out in CEPA. Please take the time to

review the draft screening assessment and let your CA Regulatory Team know if you have any questions or concerns. We will be commenting on the DSA based on member's interest.

Identification of Chemicals and Polymers as Risk Assessment Priorities (IRAP)

The Domestic Substances List (DSL) contains approximately 23,000 substances and out of that approximately 4,300 substances were [identified as requiring screening assessment](#). The categorization process was completed in 2006 and was based on information available at the time. It is one of 7 mechanisms that help to identify candidates for risk assessment. The [Identification of Risk Assessment Priorities: Results of the 2017-2018 Review and its supporting document](#) describe how the approach was applied to identify chemicals and polymers, beyond those identified through DSL categorization, as risk assessment priorities under CEPA 1999.

This review was conducted in 2017-2018 and primarily focused on identifying new information that would constitute indicators of hazard and/or exposure for the following types of substances:

- substances on Canada's DSL that have not been assessed within the last 5 years, and are not scheduled to be assessed under the CMP
- previously assessed substances that were not found to meet the criteria under section 64 of CEPA 1999, depending on the time elapsed since data/information on the substance was last reviewed
- substances that were nominated by CMP program staff as being of potential concern based on knowledge acquired through research and/or expertise gained from previous assessments
- substances identified as potentially requiring review pursuant to section 75 of CEPA 1999

After searching the pertinent sources of information, the process identified approximately 8,400 substances that fit the scope of the review and had at least one new piece of information representing potential indicators requiring further consideration.

The analysis identified substances that are:

- unlikely to require further work based on information available
- new candidates for risk assessment
- likely to require further data gathering
- likely to require further scoping / problem formulation
- subjects of ongoing international activities

Publication of the Draft Screening Assessment for the Ketones Group & the Risk Management Scope for MEK, MIBK and 2,4-PD

Environment and Climate Change Canada (ECCC) released the [Draft Screening Assessment for the Ketones Group](#) and the Risk Management Scope for MEK, MIBK and 2,4-PD on the Chemical Management Plan website. Below are the ten substances that were assessed in the Ketones Group:

1. 2-Butanone (Also known as "Methyl ethyl ketone (MEK)", CAS Registry No. 78-93-3)
2. 2-Pentanone (Also known as "Methyl propyl ketone (MPK)" CAS Registry No. 107-87-9)
3. 4-Methyl-2-pentanone (Also known as "Methyl isobutyl ketone (MIBK)", CAS Registry No. 108-10-1)

4. 2-Hexanone, 5-methyl (Also known as “Methyl isoamyl ketone (MIAK)”, CAS Registry No. 110-12-3)
5. 4-Hydroxy-4-methyl-2-pentanone (Also known as “Diacetone alcohol (DAA)”, CAS Registry No. 123-42-2)
6. 2,3-Butanedione (Also known as “Diacetyl”, CAS Registry No. 431-03-8)
7. 2-Butanone, 3-hydroxy (Also known as “Acetoin”, CAS Registry No. 513-86-0)
8. 2,3-Pentanedione (Also known as (2,3-PD), CAS Registry No. 600-14-6)
9. 2,4-Pentanedione (Also known as (2,4-PD), CAS Registry No. 123-54-6)
10. 4-Methyl-3-penten-2-one (Also known as “Mesityl oxide (MO)”, CAS Registry No. 141-79-7)

The draft screening assessment concluded that MEK, MIBK and 2,4-PD may be harmful to human health and meets the criteria of CEPA. As a result, it is proposed to add these substances to the List of Toxic Substances (Schedule 1 of CEPA). The public comment period will be closing on March 19, 2019. Cosmetics Alliance will be submitting comments based on member’s interest. Please send any feedback or comments you have to regulatory@cosmeticsalliance.ca

Informed Substitution within Canada’s Chemicals Program

Health Canada and Environment and Climate Change Canada are exploring ways to support informed substitution and drive Canadian innovation and the adoption of safer chemistry.

[Informed substitution](#) is the considered transition from a chemical of concern to safer chemicals or non-chemical alternatives and is an internationally recognized strategy for reducing health and environmental risks posed by chemicals.

Health Canada recently commissioned the Lowell Center for Sustainable Production to conduct a study to identify potential ways for Canada to advance informed substitution in a future iteration of the Chemicals Management Program after 2020. The purpose of this consultation is to solicit feedback on the proposed elements and activities outlined in the study. This feedback will be considered when planning the next phase of chemicals management in Canada.

The report does not reflect the views of the Government of Canada nor does it infer a policy intent for the future. It is being shared with Canadians for transparency, and to provide an opportunity to the public to provide additional information or considerations on the topic.

Government of Canada responds to Ontario Court Decision on Accepted Interveners for Upcoming Carbon Pollution Pricing Case

On January 16, 2019, The Minister of Environment and Climate Change Catherine McKenna [issued the following statement](#) on the occasion of the Ontario Court of Appeal’s Decision to grant intervenor status to individuals and organizations that will take part in the hearing for the Ontario Reference Case, set for April 15-18, 2019:

“We welcome the Ontario Court of Appeal’s decision to hear the vast diversity of voices - health professionals, youth, economists, Indigenous peoples, environmentalists and faith groups – that support taking climate action by ensuring it is no longer free to pollute. Carbon pollution has an impact on everyone – on our health, our jobs, and our homes. We will continue to work with all Canadians to protect the environment and grow the economy.

"Carbon pollution knows no borders. It is by working together to tackle climate change across the country that we can make a real difference. Putting a price on carbon pollution is a practical, affordable way to reduce emissions. It also ensures Canadians are better off. This year, an Ontario family of four will receive \$307 through the Climate Action Incentive."

Post-Consumer Waste Updates

Ontario Ministry Consultation on Battery MHSW Program

As previously reported, the Minister of the Environment, Conservation and Parks (MECP) has directed Stewardship Ontario (SO) to wind up the program for single-use batteries on June 30, 2020. This will transition the program to the *Resource Recovery and Circular Economy Act* (RRCEA). The Ministry will create a new Regulation. The Ministry held webinar consultations on January 9 and January 14, 2019; the [consultation slides](#) are now available. Interested companies and other stakeholders are encouraged by the Ministry to send feedback on the policy considerations that are being proposed, as well as your responses to the specific consultation questions throughout the deck on elements that could be included in the Regulation. Please email comments to Trevor.Craig@ontario.ca by February 6, 2019. Of note, Stewardship Ontario must submit a wind-up plan to the Authority no later than June 30, 2019 and will hold separate consultations with stakeholders when developing this Plan.