

Regulatory Essentials – December 22, 2021

CA's Virtual Winter Workshop A Huge Success!

Cosmetics Alliance hosted our second Virtual Regulatory Workshop on December 9th and 10th with 126 people in attendance.

Hosted by CA's Vice President and Regulatory Director Beta Montemayor (aka Féta), attendees were guided through essential updates from Health Canada's Directorates CHPSD, NNHPD and HPCD (ROEB).

Some of the key topics covered were the Self-Care Framework and an Interim Measures Update, Drug Establishment Licensing (DEL) statistics and upcoming DEL and GMP initiatives, Cosmetic Regulations & Hotlist Consultation updates and the upcoming work being done to automate the Cosmetic Notification Form.

A highlight from the event was the "Directors General Panel" featuring Natalie Page (NNHPD), Linsey Hollett (HPCD) and Roger Charland (CHPSD) joined by CA President Darren Praznik. The panel was moderated by Beta Montemayor.

The three DGs reflected on the events over the last six months such as the election, the pandemic, and a new Minister and how they have been diligently shaping the Self-Care Framework during this time.

Our members provided Health Canada with valuable feedback during the question period and had the opportunity to network with their industry colleagues and Health Canada virtually.

Our next Regulatory Workshop is scheduled for May 17th, 2021, at the Centre Mont-Royal in Montreal. Mark your Calendars now!

Health Updates

Update on End of Year 2021 Submission for OTCs and Disinfectants

This notice is for those with over-the-counter (OTC) and disinfectant active drug applications for which the review deadline falls between December 20, 2021 and January 9, 2022.

As Health Canada prepares for the year-end holiday period, many companies are temporarily closing their offices and will be unavailable to respond to Clarification Requests. Typically, Health Canada would issue a negative decision if a Clarification Response were not received by the stated deadline, which does not include an allowance for holidays.

To better accommodate temporary closures and continue the strong collaboration with industry, for all cost-recovered submissions due between December 20, 2021, and January 9, 2022, Health Canada will be shifting the review deadline by 14 days. This 14-day deadline extension

will also apply to files for which Clarification Requests were issued prior to December 20, 2021, but remain unanswered by this date.

Throughout this period, Health Canada will continue to process applications, including those with expedited review targets (submitted prior to October 1, 2021) for qualifying disinfectant drug applications. The decision to extend deadlines will support this work by allowing staff to focus on application reviews, rather than managing application deadlines individually given many companies will not be in a position to respond.

Consumer Product Enforcement Summary Report for Advance Notice of Importation

The purpose of this Compliance Verification (CV) project was to verify industry's compliance of cosmetic products imported under the Advance Notice of Importation process. For the 2020-2021 fiscal year, visual evaluation of 99 different products were carried out. The evaluation resulted in 1 recall, 1 stop distribution and 31 commitments to address non-compliance. There were 66 instances where no corrective action was required. For the complete list of products under the CV project please click [here](#).

Cosmetics Alliance Brings Together Global Experts from our Membership to Discuss Advances in Non-Animal Testing Alternatives with Healthy Environments and Consumer Safety Branch (HECS)

Cosmetics Alliance hosted a science meeting on December 16th focused on a science dialogue to review European SCCS developments and provided supplemental feedback in support of the Canadian assessment of the Homosalate Salicylates grouping.

The meeting focussed on:

- contextualizing recent developments in Europe,
- encouraging considerations of PBPK modelling to support risk assessments,
- discussing the application of NAMs to advance non-animal safety assessments for regulatory purposes,
- identifying additional scientific considerations and
- ensuring a continued collaborative scientific dialogue to support next-generation approaches to safety & risk assessments.

We are pleased to report the regulators appreciated an interest in another round of science dialogue which means they continue to work on their assessment, and they appreciated a holistic, science-based approach for further contemplation.

Cosmetics Alliance was pleased to have and thanks subject experts from member companies, Beiersdorf and L'Oreal, for presenting the NAM (PBPK) topics:

- Dr. Abdulkarim Najjar (Beiersdorf)

- Dr. Andreas Schepky (Beiersdorf)
- Dr. Sebastien Gregoire (L'Oreal)

Representation from CAC's Risk Assessment & Ingredient Safety Committee (RAIS) included:

- Beiersdorf
- Edgewell
- Estee Lauder
- Johnson and Johnson
- L'Oreal
- Procter and Gamble
- Unilever

Other trade association collaborating experts in attendance were:

- Dr. Alexandra Kowcz & Dr. Linda Loretz - Personal Care Products Council (PCPC)
- Estefania Cardamone - Cosmetics Europe (CE) – presenting developments in Europe
- Cosmetic Long-Range Science Strategy (LRSS) Homosalate Consortia

Representatives from Health Canada (HECS) and Environment & Climate Change Canada (ECCC) included

- Nicole Davidson (Director – HECS)
- Alice Luu (HECS)
- Angelika Zidek (HECS)
- Tara Barton-Maclaren (HECS)
- Matthew Gagné (HECS)
- Virginie Bergeron (HECS)
- Homeshwar Dayaram (HECS)
- Marc Demers (ECCC)

NAPRA Updated Policy on Natural Health Product Ingredients

The National Association of Pharmacy Regulatory Authorities (NAPRA) will be de-scheduling the remaining 83 natural health product (NHP) ingredients from the National Drug Schedules (NDS) in January 2022 with the exception of ephedrine and pseudoephedrine. Ephedrine and pseudoephedrine will be de-scheduled in January 2024.

In late 2019, NAPRA informed Health Canada it intended to remove all NHP ingredients from the National Drug Schedules (NDS) in several phases. More information including the phased approach can be found at: <https://napra.ca/nds-notice-board/napra-updates-its-policy-natural-health-products>

Environmental Updates

CMP Risk Assessment Publications Plan for January to March 2022

Canada's Chemicals Management Plan (CMP) program is sharing the following Risk Assessment Publications Plan to inform stakeholders of publications from January to March 2022. The program anticipates sharing the Risk Assessment Publications Plan for April-June 2022 by spring 2022. Substances of importance to CA's membership is highlighted below.

Publications targeted for January to March
1-nitropropane FSAR ^b
Alcohols DSAR ^a
Alkyl Halides DSAR ^a
Assessment of Select Hydrocarbon-based Substances DSAR ^a
Benzoxazole, 2,2'-(1,4-naphthalenediyl)bis- FSAR ^b
Esters DSAR ^a
Framework for the Risk Assessment of Manufactured Nanomaterials under the <i>Canadian Environmental Protection Act, 1999</i> ^c
Heptamethylnonane FSAR ^b
Substances Identified as Being of Low Concern Using the Ecological Risk Classification of Inorganic Substances and Biomonitoring or Rapid Screening Science Approaches ^a
Version 2.0 of the Ecological Risk Classification Approach for Prioritizing Organic Substances on the Canadian Domestic Substances List DSL that Did Not Meet Categorization Criteria (ERC2) ^c

^a Draft Screening Assessment Reports (DSAR) presenting information on health and ecological considerations and, where criteria under s. 64 are proposed to be met, Risk Management Scope documents.

^b Final Screening Assessment Reports (FSAR) presenting information on health and ecological considerations and, where criteria under s. 64 are met, Risk Management Approach documents.

^c Science-based approach document.

Note: Group names are not final and may change

Government of Canada Moving Forward with Banning Harmful Single-use Plastics

On December 21, the Minister of Environment and Climate Change, the Honourable Steven Guilbeault, and the Minister of Health, the Honourable Jean-Yves Duclos, announced that draft regulations prohibiting certain single-use plastics have now been published for public comment. As previously communicated in the proposal specific to the single use plastics, the draft regulations list the six single use plastic items. The first regulatory proposal outside of microbeads is to address the management of plastics in the Canadian context. One key highlight which is not part of proposal but is mentioned in the preamble note is the reference to recycled content target for 2030. Cosmetics Alliance will be working with membership in the new year to help shape our engagement on recycled content considerations. The full report can be viewed [here](#).

Update on Substances Search Tool

The Substances Search tool on the Government of Canada website has been updated with information current as of December 6, 2021. Environment and Climate Change Canada strives to update the Substances Search tool when possible, the latest substance lists are available from the Substances Management Information Line (substances@ec.gc.ca).

CMP Implementation Table a Glance

The Chemicals Management Plan implementation table for 2021 – 2024 was published. This table summarizes the governments plan for the next 4 years including deliverables, rationale for action and timelines. The full table can be viewed [here](#).

Publication of Sixth Biomonitoring Report and New Fact Sheets

Environment and Climate Change Canada released the [Sixth Report on Human Biomonitoring of Environmental Chemicals in Canada: Results of the Canadian Health Measures Survey Cycle 6 \(2018-2019\)](#), along with 8 [biomonitoring fact sheets](#) for a selection of chemicals, which occurred on December 14, 2021.

The Canadian Health Measures Survey (CHMS) is a comprehensive direct health measures survey conducted by Statistics Canada, in partnership with Health Canada and the Public Health Agency of Canada. The CHMS includes a biomonitoring component, funded by Health Canada, which measures the levels of environmental chemicals in individual samples of blood and urine. Health Canada's National Biomonitoring Program reports are key deliverables under the Chemicals Management Plan.

The Sixth Report contains summary data for 79 environmental chemicals measured in cycle 6 of the CHMS. It features data for the same set of chemicals presented in the previous Fifth Report, except for volatile organic compounds (VOCs), which were excluded for cycle 6. The report does not address any health outcomes, provide analyses or conclusions, or recommend policy direction. It is strictly a technical document that outlines objectives, describes the survey design and methods, and provides descriptive summaries of measured environmental chemicals, along with approximately 130 data tables.

New this year is the publication of biomonitoring fact sheets that highlight changes in chemical exposures over time, distributions across age groups, differences between males and females, and comparisons between the Canadian population and other populations in Canada and the United States. Eight fact sheets have been released this year on arsenic, cadmium, lead, mercury, PFAS, DEHP, bisphenol A (BPA) and parabens.

Cosmetics Alliance wants to continue to lend support to the biomonitoring program as it is a helpful tool to inform exposure and risk assessment moving forward. Of particular interest in the data regarding PFAs as the information in the assessment will help shape future CMP assessment regarding large group of chemicals. This information will also be important to serve to supplement and contextualizing on going 'citizen science' efforts concerning the potential presence of PFAS chemicals in consumer products and the environment writ large. The

summary factsheets (8 published) are also very helpful 'snap shots' outlining trends in relation to these data – with particular focus on those chemistries that are often considered priority environmental chemicals for consideration.

Data files are also available through [Statistics Canada's Research Data Centers](#) (RDCs).

Cosmetics Alliance Updates

Cosmétiques 101- Introduction aux cosmétiques au Canada

Date: Thursday, January 20, 2022; Jeudi le 20 janvier 2022

Time: 2:00 p.m. - 4:30 p.m.; 14h00 à 16h30

Cost: 1-4 delegates Member: \$250 each Non-member: \$395 each

5-10 delegates Member: \$225 each Non-member: \$370 each

Over 10 delegates: \$200 each Non-member: \$345 each

Please note the training session is in French and is open only to Cosmetics Alliance member companies that have an officially declared office in the province of Quebec.

Designed for:

- New Employees
- New Cosmetics Alliance Members
- Refresher Course

Objectives

- Learn the language of cosmetics in Canada.
- Understand the set-up of Canadian Law.
- Overview of the Cosmetic Regulations.
- Enable attendees to access the Canadian market.

Training will include exercises, a quiz and a training certificate for your training file.

Only those electronically registered will be able to take the quiz and receive a training certificate.

[Register](#)