

Regulatory Essentials – March 21, 2019

Cosmetics Alliance Update

Free Webinar: Microplastics – Proposed European Chemicals Agency

Cosmetics Alliance will be hosting a free webinar with the Director General of Cosmetics Europe, John Chave and CA's Regulatory Director, Beta Montemayor, to discuss the [Proposed Restriction Dossier](#) under Annex XV of the European Chemical Management Program (REACH) recently published by the European Chemicals Agency (ECHA). These restrictions have potentially far-reaching and significant consequences that could affect many polymeric ingredients that are critical to the performance of a majority of products in the personal care products industry.

Please register for the webinar to learn about the implications of the Dossier for the European and global industry.

Date: Tuesday, April 2, 2019

Time: 9:00 - 10:30 a.m.

[Register](#)

Register for the Spring Regulatory Workshop

Cosmetic Alliance Canada's Regulatory Workshops provide members with the opportunity to stay up-to-date and informed on "everything regulatory". You will not want to miss this opportunity to hear from government officials and Cosmetics Alliance staff first-hand on issues that will directly affect your business. Cosmetics Alliance will be hosting a Member Engagement Session at the end of the Workshop followed by a reception so be sure to attend for the whole day.

Key Updates from:

- Consumer Product Safety Directorate (CPSD)
- Natural and Non-prescription Health Products Directorate (NNHPD)
- Regulatory Operations and Enforcement Branch (ROEB)
- Self-Care Framework Team
- Cost Recovery

[Preliminary agenda](#)

[Register](#)

Health Updates

NNHPD's Client Service Update – Auto Response Details

NNHPD has updated its automatic response to acknowledge receipt of emails. As result of a high volume of inquiries the automatic response now says it may not meet the current 10-day service standard for providing a response. Also, note that due to the high volume of inquiries NNHPD will not respond to status update enquiries if the application of interest is still within the

performance standard indicated below. Acknowledgement letter will only sent for Class II and Class III product license applications.

PRODUCT LICENCE APPLICATION PERFORMANCE STANDARD

In order to ensure the NNHPD has sufficient time to reliably verify that all monograph parameters are met prior to issuing a licensing decision, performance standards apply for product licence application. They are as follows:

- Class I applications or amendments: **60 calendar days**
- Class II applications or amendments: **90 calendar days**
- Class III applications: **210 calendar days** (30 days for screening + 180 days for review) remains unchanged.

If the performance standard of your application has been exceeded and you have not received a regulatory decision or correspondence, please ensure the following information is provided in order to receive an update:

- Product/brand name or Site name ~as appropriate~
- Application type
- Product Class I, II or III and new submission, notification or amendment
- Site Stream I, II or III
- New or supplemental drug submission
- Date of submission or date received by NNHPD
- Company name and code
- Method of delivery

1. EPOST CONNECTTM

Applications need to be sent to the 'New Applications' conversation. Applications are not processed if sent to the 'Correspondence' conversation.

2. MAIL

The NNHPD is not responsible for packages sent to its former address (2936 Baseline Road).

3. COURIER

The courier company should provide you with a confirmation of delivery

Health Canada's Misleading Advertising or Marketing C&E Campaign

Health Canada has started a Compliance & Enforcement Campaign for misleading advertising or marketing of drugs and devices to Canadians. This may include claims that do not provide a balanced representation of benefits and risk or are not consistent with the terms of market authorization of the product. The webpage [Illegal Marketing of Drugs and Devices](#) contains information on the impact of illegal marketing in Canada, filing a marketing complaint, marketing

techniques, illegal marketing practices and [more](#). CA advises members to review this new campaign.

Health Canada Finalizes Regulations to Provide Public Access to Clinical Information on Drugs and Medical Devices

On March 20, 2019 Health Canada will publish final regulations that allow for the public release of [clinical information on drugs and medical devices](#). Clinical information will be made available through Health Canada's new [Clinical Information Portal](#) as of March 13, 2019. At launch, the portal will include clinical information on a small number of products, provided by volunteer companies in advance of the final regulations. Health Canada will consult manufacturers to ensure that confidential and personal information is removed before the department releases any information. Health Canada aims to release information about drugs within 120 days of completing the review of a drug submission.

Regulatory Transparency and Openness Framework and Action Plan Report for 2017-2018

On March 7, 2019 Health Canada released its Regulatory Transparency and Openness Framework Action Plan Annual Report for 2017-2018. Below are the key highlights.

During the 2017-2018 period, HC had 11 priorities, these are the ones relevant to our personal care products. Indented bullets are HC's action on the item:

- Engage Canadians in modernizing the regulation of self-care products

The Department will continue to engage consumers and stakeholders on the development of a modernized approach to the regulation of self-care products through a series of in-person and online consultation sessions.

- o In-person and online consultations with Canadians were held

- Provide stakeholders with up-to-date information about the activities of Health Products and Food Branch scientific advisory bodies

Health Canada will provide updated online information about the meeting activities of its Scientific Advisory Panels and Scientific Advisory Committees. This will include information about the topics these bodies discussed, when they meet, and decisions that are made at meetings.

- o Online info was made available

- Develop and implement policies and procedures for sharing Confidential Business Information related to therapeutic products

The Department will develop and implement a fair, consistent and effective process for Health Canada's decision-making regarding disclosure of Confidential Business Information related to therapeutic products, and will create opportunities for stakeholder input as this work is being developed

- o HC published guidance and maintains a process (which was consulted on) for eligible requesters to obtain CBI for therapeutic products.

In addition to the items above, HC also engaged stakeholders on the development of Cannabis Regulations.

Self-Care Product Framework - Timing Update

Further to our February 26th [member update](#) regarding Health Canada's outreach to stakeholders to discuss timing of the amendments required to implement the Self-Care Products Framework, Cosmetics Alliance has submitted formal written comments. Members can view our letter here: [Cosmetics Alliance Comments – Self-Care Framework Timing March 6 2019](#).

Our input includes the various comments provided to us by member companies and our response was coordinated with allied trade associations. Health Canada is now reviewing our input and will report back to us with their revised plans.

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

Consumer Product Safety Program – Annual Surveillance Report and Five-year Surveillance Report

Below are the key highlights from each report.

2017 Annual Report:

- 164 reports related to cosmetics were reported in 2017
- Of these, 103 mentioned a non-fatal injury
- The top 10 cosmetic product reported are (I can provide the details of these):
 - Moisturizers
 - Cleansers
 - AP/deodorants
 - Make up
 - Shampoo
 - Bath products
 - Permanent hair colour
 - Adhesives
 - Conditioners
 - Tooth whiteners

Most of the reports related to "irritations or allergic reactions"

Most, if not all in some categories, were classified as "minor or moderate" in severity. Only a few in total were considered "severe"

15 of the reports were from industry

Five-Year Report (2013-2017)

- This is the first publicly available 5-year report Health Canada has published
- 468 reports were received during this period
- 1 death. This death was due to poisoning associated with a hairspray product.

- 293 mentioned non-fatal injury
- The top 10 cosmetic product reported are:
 - Moisturizers
 - Cleansers
 - Makeup
 - Bath products
 - Cosmetic adhesives
 - Shampoo
 - AP/deodorants
 - Fragrance products
 - Permanent hair colour
 - Conditioners

Incident reporting increased over the time period for both consumer products and cosmetics due to awareness of consumer reporting.

Six New Consumer Product Enforcement Summary Reports

Health Canada has posted six new Consumer Product Enforcement Summary Reports on its website. The six reports are:

1. Second-Hand Products Reports
2. Consumer Chemicals and Container Report
3. Carriages and Stroller Report
4. Surface Coating Materials Report
5. Toys Report
6. USB Chargers Report

Of relevance to the personal care products industry is the Second-Hand Products Report. The purpose of this Cyclical Enforcement (CE) project was to verify the used-product industry's compliance under the CCPSA and its regulations, the Food and Drugs Act as it relates to cosmetics and the Cosmetic Regulations. For this project, compliance of select second-hand products was determined through an inspection process by which Health Canada inspectors visited establishments and visually inspected relevant products. Compliance with the requirements of the CCPSA and its regulations, and the FDA and the Cosmetic Regulations was verified by Health Canada inspectors on-site.

Prior to initiating this CE project, the CPSP carried out a market survey to identify second-hand companies in Canada. Targets were then selected from that list of companies.

Over the course of the 2017-2018 fiscal year, visual evaluation of 103,292 different products was carried out. The evaluation resulted in 321 stop sales, stop distributions, commitments, corrections, disposals, or forfeitures. There were 167 instances where no corrective actions were required. Please view the [report](#) to view the results of the CE project.

Environmental Updates

Cosmetics Alliance Submits Comments for the Talc Draft Screening Assessment

On March 8, 2018 the Draft Screening Assessment Report (DSAR) of Talc was released suggesting that Talc was found to be a potential human health risk through inhalation exposure through certain cosmetics and self-care products and possible association with perineal use of such products and ovarian cancer. CA created a Talc Science Task Force containing experts in the inhalation and ovarian cancer to meet on a bi-weekly basis to draft comments for the DSAR. On February 6, 2019 CA submitted comments for the DSAR. CA's comments were focused on important scientific deficiencies in the DSAR that question the overall validity of the review and its conclusions on inhalation and ovarian cancer risks.

Summary of comments pertaining to non-cancer inhalation risks:

- Lack of transparency in the documentation of assumption and rationale for critical study selection shows significant uncertainty in the draft risk assessment
- Alternative approaches and suggested refinements in exposure assessments reveal adequately protective Margin of Exposure (MoE) for local lung effects (based on internationally recognized Notes of Guidance) for cosmetic and self-care product use scenarios of concern.
- Revised risk characterization (taking into account our proposed alternative approaches) reinforce previous documentation (voluntary member survey) submitted by CA Canada and re-affirms that talc in cosmetic and self-care products are formulated so not to present an inhalation risk

Summary of comments for perineal talc use and ovarian cancer:

- Prospective cohort studies consistently report NO overall increase in relative risk with regards to ovarian cancer, followed over many years of perineal talc use.
- the collective epidemiologic data DOES NOT support a causal association between talc use and ovarian cancer

Following the submission of comments, we have requested for a follow-up meeting for April to review the technical input in person with Environment and Climate Change Canada and Health Canada before the release of the Final Screening Assessment. If you would like a copy of CA's commentary for the DSAR please email regulatory@cosmeticsalliance.ca.

Canadian Environmental Sustainability Indicator (CESI) Webinar

Environment and Climate Change Canada's Sustainable Development Office is hosting a free webinar on indicators. During this webinar, you will learn more about the [Canadian Environmental Sustainability Indicators](#) (CESI) program and the use of its indicators to track the progress of the goals and targets of the Federal Sustainable Development Strategy. You will have the opportunity to share information on available data to make the indicators more comprehensive and robust and discuss research and development to help fill the gaps and improve the tracking of progress towards sustainable development. You can register for the webinar by clicking [here](#).

When: Friday, March 22, 2019 from 12:00 p.m. to 1:00 p.m. (EDT)

[Reducing Litter and Waste in Our Communities: Discussion Paper](#)

The Ministry of the Environment, Conservation and Parks shared the progress that has been made on policy related to the management of waste.

The ministry released its [Preserving and Protecting our Environment for Future Generations – A Made-in-Ontario Environment Plan](#) on November 29, 2018 to protect the air, land and water and reduce litter and waste while lowering greenhouse gas emissions and helping communities protect themselves from climate change.

Expanding on the Environment Plan, the ministry is currently seeking feedback on the Reducing Litter and Waste in Our Communities: Discussion Paper. The discussion paper provides a road map for the next few years to enable the province to move forward with a clear, comprehensive and outcome-based approach to reducing litter and waste in our communities.

The discussion paper proposes eight key areas for action:

1. Prevent and reduce litter in our neighbourhoods and parks.
2. Increase opportunities for Ontarians to reduce and divert waste at home, at work and on the go.
3. Make producers responsible for the waste generated from their products and packaging.
4. Reduce and divert food and organic waste from households and businesses.
5. Reduce plastic waste going into landfills and waterways.
6. Provide clear rules for compostable products and packaging.
7. Recover the value of resources in waste.
8. Support competitive and sustainable end-markets for Ontario's waste.

The discussion paper has been posted on the [Environmental Registry](#) (<https://ero.ontario.ca/notice/013-4689>) for a 45-day public review and comment period from March 6, 2019 to April 20, 2019. The ministry would like to invite you to review the proposed discussion paper on the Environmental Registry and share your written comments.

Various Publications in the Chemical Management Plan

On March 8, 2019 the Chemical Management Plan released several Final Screening Assessment Reports (FSAR) for [Arenes Group](#), [Carboxylic Acids Group](#) and [Carboxylic Acid Anhydrides Group](#). The groups that are relevant to the personal care products industry is Carboxylic Acids Group and Carboxylic Acid Anhydrides Group. The substances that were under review for Carboxylic Acids Group were:

Substances in the Carboxylic Acids Group

CAS RN	Domestic Substances List name	Common name
79-09-4	Propanoic acid	Propionic acid
107-92-6	Butanoic acid	n-Butyric acid
112-05-0	Nonanoic acid	Nonanoic acid
144-62-7	Ethanedioic acid	Oxalic acid

It is concluded that propionic acid, *n*-butyric acid, nonanoic acid, and oxalic acid do not meet any of the criteria set out in section 64 of CEPA.

The substances that were under review for Carboxylic Acid Anhydrides Group were:

Substances in the Carboxylic Acid Anhydrides Group

CAS RN	Domestic Substances List name	Common name
85-44-9	1,3-Isobenzofurandione	Phthalic anhydride
108-31-6	2,5-Furandione	Maleic anhydride
552-30-7	5-Isobenzofurancarboxylicacid, 1,3-dihydro-1,3-dioxo-	Trimellitic anhydride

It is concluded that phthalic anhydride, maleic anhydride and trimellitic anhydride do not meet any of the criteria set out under section 64 of CEPA.

Draft Screening Assessment of DTMP

[The Draft Screening Assessment Report](#) for phosphonic acid, [[(phosphonomethyl) imino]bis[2,1-ethanediylnitrilobis(methylene)]]tetrakis- (DTPMP) was published on March 16, 2019 for a 60-day comment period ending on May 16, 2019. It is proposed that DTPMP does not meet any of the criteria set out in Section 64 of CEPA. Cosmetics Alliance will be commenting based on membership interest. Please email regulatory@cosmeticsalliance.ca if you have any comments.

Chemicals Management Plan Progress Report: Issue 11 Published

On March 14, 2019, the eleventh issue of the Chemicals Management Plan (CMP) Progress Report covering activities between June and December 2018. It also provides information about future events, dates of interest and future engagement opportunities. The report is produced jointly by Environment and Climate Change Canada (ECCC) and Health Canada (HC). Some key highlights are included in the report on CMP, Gathering Initiatives, Revised In-Commerce List, Asbestos Regulation, Triclosan and more. Please take the time to review the [report](#) and let your CA Regulatory Team know if you have any concerns.

Post-Consumer Waste Updates

Reminder to register for April 2, 2019 Ontario MHSW Wind Up Plan Consultation

A Steward-focused consultation will take place Tuesday, April 2, 2019, 10:00 - 12:00 p.m. EST. [Click here to register](#). See the previous Regulatory Essentials for full details on this Municipal Hazardous or Special Waste (MHSW) consultation. See also the Stewardship Ontario [MHSW Wind Up web page](#). Following the consultation webinar, stakeholders will have until Thursday, May 1, 2019, to submit written feedback. Questions may be emailed to consultation@stewardshipontario.ca.

CSSA Ready to report webinar materials now posted

The Canadian Stewardship Services Alliance (CSSA) Webinar replays, presentations and other information for new and experienced stewards are now available on [CSSA's 2019 Reporting Resources](#) webpage.

New Ontario Consultation on Reducing Litter and Waste - Comments due April 20, 2019

On March 6, 2019 the Ontario Ministry of the Environment, Conservation and Parks announced it is expanding on the [Preserving and Protecting our Environment for Future Generations – A Made-in-Ontario Environment Plan](#) and is currently seeking feedback on the Reducing Litter and Waste in Our Communities: Discussion Paper. The discussion paper has been posted on the

[Environmental Registry \(https://ero.ontario.ca/notice/013-4689\)](https://ero.ontario.ca/notice/013-4689) for a 45 day public review and comment period from March 6, 2019 to April 20, 2019. The discussion paper provides a road map for the next few years to enable the province to move forward with a clear, comprehensive and outcome-based approach to reducing litter and waste in our communities.

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The ministry would like to invite you to review the proposed discussion paper on the Environmental Registry and share your written comments and feedback on how the province can achieve positive outcomes around the problem of waste and litter in Ontario.