

Regulatory Essentials- April 18, 2018

Cosmetics Alliance Update

Spring Regulatory Workshop – Highest Attendance in 5 Years!

Cosmetics Alliance successfully hosted another Spring Regulatory Workshop on April 12, 2018 at the Hotel Omni Mont-Royal in Montreal. With over 100 attendees the workshop was found to be a very informative and enlightening event. Attendees gained valuable insight into the current industry landscape from both industry and government experts with the most up-to-date information.

Highlights included:

- Important updates on the Cosmetic Ingredient Hotlist, Self-Care Products Framework, Management of Product License Applications for NHPs
- Status of the Sunscreen Pilot
- Updates on Cosmetics Alliance service improvements including communications and committees

Speakers also presented on the following topics:

- Consumer Product Safety Directorate Updates
- Natural and Non-prescription Health Products Directorate Updates
- Regulatory Operations & Regions Branch Updates

As always at our regulatory events, members had the unique opportunity to network with government and industry colleagues, which promotes continued engagement after our workshop ends. For more information please see Cosmetics Alliance monthly newsletter.

If you want to learn more about all things regulatory, please join us at our next regulatory workshop on October 10th at the King Edward Hotel in Toronto. Mark your calendars now so you do not miss out on this valuable event.

Health Update

Expansion of the Sunscreen Pilot - Letter to the Deputy Minister

Cosmetics Alliance has been actively working on expanding the Sunscreen Pilot to other product categories and trusted jurisdictions. In this approach Cosmetics Alliance is in the process of escalating the expansion of the Pilot to the Deputy Minister Simon Kennedy after conversations with RORB. A letter to Simon Kennedy is going out on April 18, 2018. The letter emphasises the importance of the Pilot as it provides the opportunity for companies importing sunscreens from the U.S. to apply modified options for identification testing in Canada of finished sunscreen products. In the interim PHAC is evaluating the Pilot with the 360-degree Analysis. If you are interested in expanding the Sunscreen Pilot please let your Cosmetics Alliance Regulatory Team know at regulatory@cosmeticsalliance.ca.

AHAs Technical Requirements Updated

At Cosmetics Alliance Spring Regulatory Workshop, the Consumer Product Safety Directorate (CPSD) announced the update of the Alpha Hydroxy Acids (AHA) Technical Requirements. As you may recall the technical requirements for AHAs were:

Ingredient information		Restrictions
Chemical	Conditions of use	Warnings and cautionary statements
Alpha-hydroxy acids	<p>Permitted at total concentrations equal to or less than 10%, and a pH equal to or greater than 3.5.</p> <p>Preparations containing concentrations of AHAs between 10% and 30% or a pH between 3.0 to 3.5 may be permitted for professional use if the manufacturer provides Health Canada with evidence of their safety including:</p> <ol style="list-style-type: none"> 1. pH levels 2. AHA concentrations 3. directions for use 4. clinical studies demonstrating minimal skin irritation <p>Preparations intended to be diluted in bath water may contain levels of citric acid exceeding 10%.</p>	<p>All skin products containing AHAs at concentrations equal to or greater than 3% shall carry cautionary statements to the effect:</p> <p>“Use only as directed.”, “Avoid contact with the eyes.”, “If irritation persists, discontinue use and consult a physician.”, “It is recommended that prior to exposure to the sun, users cover areas where AHAs have been applied with sunscreen.”, “Contact of the product with the skin must be of limited frequency or duration.”</p>

The updated AHAs Technical Requirements:

Type of Preparation	Total AHAs Concentration and pH levels	Cautionary Statements	Clinical Studies
Consumer Use	≥ 3% and ≤ 10% and pH ≥ 3.5	Yes	No
Professional Use	>10% and ≤ 30% <u>or</u> pH between 3.0 and 3.5	Yes	Yes

An updated version of the Technical Requirements for products containing alpha hydroxy acids will be available through regional product safety officers. Cosmetics Alliance encourages interested stakeholder to request for the updated guidance document.

Advanced Notice of Importation Pilot Project

The [Advanced Notice of Importation \(ANI\) Pilot](#) is still on going. For the duration of the 1-year pilot, regulated parties may use the Advance Notice of Importation Form to provide Health Canada with advance notice of multiple products imported within a 3 month period. At Cosmetics Alliance Spring Regulatory Workshop, Consumer Product Safety Directorate (CPSD)

announced some updates to the ANI Pilot. As you may recall the ANI is valid for maximum of 3 months. CPSPD has now extended the blanket period of importation from 3 months to 6 months.

North America Consumer Product Safety Summit

On April 10, 2018, Health Canada announced that the U.S. Consumer Product Safety Commission (U.S. CPSC) will host the fourth trilateral North America Consumer Product Safety Summit, open to stakeholders May 4th, 2018, at the U.S. CPSC's Headquarters in Bethesda, MD. A range of consumer product safety topics will be discussed including international collaboration, e-commerce, the Internet of Things and lithium-ion batteries. There will also be a panel discussion of stakeholder perspectives on product safety. Cosmetics Alliance encourages any interested stakeholder to [register](#) for the summit. For more information please contact hc.ccpa-lcspc.sc@canada.ca.

Environment Update

Email Transformation Initiative

As part of the Government of Canada email transformation initiative the contact information for the Chemical Substances section of the Chemical Substances website has changed from chemicalsubstanceschiques@hc-sc.gc.ca to HC.chemicalsubstances-chimiques.SC@canada.ca. More information on this initiative can be found [here](#). Please also note that the Health Canada and Environment and Climate Change Canada Websites, including the former Chemical Substances Website have been migrated to the [Government of Canada's Website](#).

Mail Delivery Service Changes

As of April 1, 2018, the mail delivery service for Environment and Climate Change Canada has been changed and all packages and documents must be shipped as follows:

Delivery by Messenger:

Executive Director, Program Development and Engagement Division
351 St-Joseph Boulevard
Place Vincent Massey
Gatineau, Quebec
K1A 0H3

Mailing Address:

Executive Director, Program Development and Engagement Division
Environment and Climate Change Canada
Gatineau, Quebec
K1A 0H3

Revised In Commerce List (R-ICL)

On April 7, 2018, the [Notice of Intent](#) announcing the closure of the nomination of substances on the R-ICL was published in the Part 1 of the Canada Gazette with a 60-day comment period. Cosmetics Alliance is concerned with the scope of the Notice of Intent and will be engaging with

officials for further clarification on the notice as well as the termination process. Cosmetics Alliance encourages any stakeholder who submitted nominations to review the Notice of Intent and submit any comments during the 60-day comment period. Cosmetics Alliance wants stakeholders to send in any concerns they may have around the notice and the termination process to regulatory@cosmeticsalliance.ca.

Second Phase of Polymer Rapid Screening

As part of the Chemicals Management Plan (CMP), the Government of Canada is assessing certain [polymers](#) under CEPA. Three hundred and thirty-six polymers were identified as candidates for a second phase of polymer rapid screening. The ecological component of the [second phase of polymer rapid screening](#) consisted of four main steps. The first step involved identifying polymers which are not likely to be of ecological concern based on low reported import and manufacture quantities. The second and third steps of the process involved identifying polymers that are likely to have water extractability greater than 2% by weight and determining whether these polymers contain reactive functional groups. The final step involved applying two exposure scenarios using assumptions that are protective of the environment and comparing exposure to a conservative acute ecotoxicity value for each polymer. In total, 32 of the polymers evaluated under the second phase of the ecological polymer rapid screening approach were identified as requiring further screening assessment from an ecological perspective. A list of the 32 polymers is provided in Appendix A. Furthermore, 299 polymers were identified as being of low ecological concern. Cosmetics Alliance encourages stakeholders and manufacturers who use polymers to review the Second Phase Rapid Screening and let your CA Regulatory Team know if you have any concerns at regulatory@cosmeticsalliance.ca.

Publication of SNUR-SNAc Educational Primer

On April 13, 2017, Environment and Climate Change Canada (ECCC), Health Canada (HC) and the Environmental Protection Agency (EPA) of the United States announced the publication of an [educational primer on Significant New Activity \(SNAc\)](#) provisions and Significant New Use Rules (SNURs). The Primer was developed as part of the SNAc-SNUR Work Stream of the Regulatory Cooperation Council (RCC) Chemicals Management Work Plan. The Primer addresses a gap of the need for consistent and effective approaches to compliance promotion for SNAcs and SNURs. The educational primer aims to promote a better understanding by stakeholders of regulatory aspects of SNAcs and SNURs. Easy to use information has been compiled for stakeholders about each program to assist them in determining their compliance obligations. Cosmetics Alliance encourages stakeholders conducting business in Canada or the United States to review the compliance primer to understand how SNAcs and SNURs may apply to substances in Canada and in United States.

Post-Consumer Waste Updates

Municipal Hazardous or Special Waste (MHSW) Program Wind Up Announced

On Thursday, April 12, 2018, the Ontario Minister of the Environment and Climate Change Canada (ECCC) issued direction to Stewardship Ontario (SO) to wind up the Municipal Hazardous or Special Waste (MHSW) Program by December 31, 2020. SO must submit a plan no later than June 30, 2019. This wind up will allow the transition of materials collected under the program to individual producer responsibility under the *Resource Recovery and Circular Economy Act, 2016*. Read the Minister's letters:

- [Minister's Letter to SO directing Wind Up of MHSW Program, April 12, 2018](#)
- [Addendum to the Minister's Direction Letter to Wind Up the MHSW Program, April 12, 2018](#)
- [Minister's Letter to RPRA re: Wind Up of MHSW Program, April 12, 2018](#)

Information related to the program wind up and future consultations will be posted to the [Program Wind Up page](#) when available. Until the wind up date, the Municipal Hazardous or Special Waste Program will continue to operate without disruption. This includes the operation of the Industry Stewardship Plans managed by the Automotive Materials Stewardship, the Product Care Association and SodaStream. Please contact Stewardship Ontario directly for any operational inquiries at werecycle@stewardshipontario.ca.

Program Updates - Resource Recovery and Circular Economy Act

The direction to wind up the MHSW program follows the recently published [Tires Regulation under the Resource Recovery and Circular Economy Act, 2016 \(RRCEA\)](#). The Used Tires Program, operated by Ontario Tire Stewardship (OTS) under the Waste Diversion Transition Act, 2016, is to cease operation on December 31, 2018, followed by the wind up of OTS as a corporation. The Minister also recently initiated wind up of the [Waste Electrical and Electronic Equipment \(WEEE\) Program WEEE Program](#). Ontario Electronic Stewardship (OES) must submit a wind-up plan for the WEEE Program no later than December 31, 2018, and the WEEE Program is to cease operation on June 30, 2020. Plans for changes to the Blue Box Program Plan are currently on hold. However, and [Amendment to Regulation 344/90 \(Disposable Containers for Milk\)](#) is now in effect, and provides options for milk producers to use containers that are widely accepted in recycling programs or are managed through a deposit return program.