

## Regulatory Essentials – July 17, 2019

### Cosmetics Alliance Updates

Canada Hosts World Cosmetic Regulators at ICCR-13 in Montreal

Hosted by Health Canada and Cosmetics Alliance Canada, the International Cooperation on Cosmetics Regulation (or "ICCR"), held its 13th annual session in Montreal, Canada from July 9th to 12th, 2019. ICCR is an initiative of cosmetic regulators from around the world and works to coordinate and align the regulation of cosmetics on an international basis. The goal is to ensure the highest level of global consumer protection, while minimizing barriers to international trade.

Member jurisdictions include the European Union, United States, Canada, Japan and Brazil with Colombia, Israel, South Korea, Taiwan, and Thailand participating as observers. Collectively, these countries represent about 60% of the world's cosmetics market! Please take a look at our [ICCR Special Report](#) which contains more details of the event.

### Health Updates

#### Consumer and Hazardous Product Safety Directorate – 2018 Annual Surveillance Report

This [report](#) describes the surveillance findings gathered by the Consumer Product Safety Program (CPSP) within Health Canada. The CPSP is responsible for the administration and enforcement of the Canada Consumer Product Safety Act (CCPSA) and its regulations, as well as cosmetic-related provisions of the Food and Drugs Act (FDA) and the Cosmetic Regulations. The purpose of the CCPSA is to protect the public by addressing or preventing dangers to human health or safety that are posed by consumer products in Canada, including those that circulate within Canada as well as those that are imported. A total of 2355 incidents were reported for consumer products from consumers and industry. Cosmetics does not fall in the top 10 category of incident reporting.

#### Quarterly Consumer Product and Cosmetics Reports – Q4 2018-19

The Consumer Product Safety Directorate regularly receives [reports](#) on human health or safety concerns related to consumer products and cosmetics. A total of 718 reports were received with 44 reports received for cosmetics. The top three injury types were irritations, cuts and burns.

#### Publication of the Revised Bundle 10 Monographs to Address “Statements to the Effect Of”

The Natural and Non-prescription Health Products Directorate (NNHPD) [updated](#) the following monographs to reflect the changes to the “Statements to the Effect of”:

1. Betaine / Betaine hydrochloride
2. Choline
3. Chondroitin Sulphate
4. Corn & Callus Remover
5. Elder - Sambucus
6. Glucosamine hydrochloride
7. Hydrocortisone Topical
8. Lemon Balm
9. Phosphatidylserine
10. Soy Flour

11. Soybean Extracts and Isolates
12. Thyme - Oral
13. Wart Remover

Please note that the NNHPD has defined appropriate subpopulations in the Wart Remover and Corn and Callus Remover monographs as Children 2-11 years, Adolescents 12-17 years and Adults 18 years and older. This adjustment is required in order to be able to validate the subpopulation information in the Natural Health Product Licence Application Form.

Please visit [What's New](#) Page to find a listing of modifications to the Natural Health Products Ingredients Database (NHPID) since the last update.

### Management Changes at NNHPD

Following on the recent changes to Natural and Non-prescription Health Products Directorate (NNHPD) management team, there are some additional updates.

Lisa Lange will be joining the NNHPD to take on the role of Director of the Bureau of Product Review and Assessment (BPRA) starting August 6<sup>th</sup>, 2019. Lisa comes from the Marketed Health Products Directorate where she is Director of the Office of Policy, Risk Advisory, and Advertising.

With respect to the Stakeholder Engagement Division, Curtis Lockett will be acting as the interim manager until a replacement can be confirmed. In the meantime, please continue to route all correspondence to the NNHPD Consultation [hc.nnhpd.consultation-dpsnso.sc@canada.ca](mailto:hc.nnhpd.consultation-dpsnso.sc@canada.ca).

### Consumer Products Safety Directorate has Changed its Name

The Consumer Product Safety Directorate has changed its name to Consumer and Hazardous Products Safety Directorate. The official name change will be announced in the coming weeks.

### Client Services and Web-Based Product Licence Application Update

The Natural and Non-prescription Health Products Directorate (NNHPD) held a teleconference call on July 3, 2019 with industry associations. The purpose of this phone call was to provide an update on the work to improve our Client Services since the teleconference held on April 10, 2018. Additionally, Alysyn Smith provided a status update on the web PLA.

## **1. Client Services**

### **Recap of April teleconference:**

During the April call, we provided an update of the changes made to date to improve the predictability of our client services. Specifically, we took the following action:

- Developed Q&As for three of the most frequently asked questions.
- Carried out blitzes to bring down the backlog of inquiries.

- Reviewed the resources assigned to the client services function and made adjustments.
- Identified a short list of 'frequent' inquirers and have been proactively engaging with them to understand what is driving the large number of inquiries and solicit suggestions for improving the client services.

Following the call, associations were sent an email, which provided a summary of the phone call and confirmed next steps that would be taken. You were encouraged to share this summary with your members, along with the Q&As and tips attached.

**Action taken since April:**

Since the April call, NNHPD has taken the following measures:

- We updated the auto-reply function to reference the new MAP, include tips for interacting with our client services (i.e., subject headings), and guidance on submitting inquiries related to technical or system issues.
- We did not receive any feedback on the Q&As shared following the last call, so those have not changed since the last versions sent to you.
- NNHPD provided email links regarding specific inquiries in the NHP MAP email. The links have pre-populated text in the subject field that is needed for NNHPD to efficiently respond to inquiries.
- We have increased the number of resources assigned to the client services function, and are pursuing an additional hire to lead this group.

**Current State of Client Services:**

Last fiscal year, NNHPD received over 12,000 email inquiries, with an average of approx. 1,100 inquiries per month. Since April 2019, there has been a steady number of requests for an update on the status of an application. Of the inquiries due in June, approximately 25% have received a response within the current 10-business day performance standard.

**Follow-up from July 3<sup>rd</sup> teleconference:**

During the July 3<sup>rd</sup>, 2019 teleconference, we discussed additional ways NNHPD can improve client services, including the approach to prioritizing the following incoming inquiries: Class I status updates, Pre-submission meeting requests and Trading Partner and Company Registration Requests. There was general support for the way NNHPD has been prioritizing inquiries.

Associations were requested to carry out the following actions:

- Associations to share this message and its attachments with their members.

- Associations to provide suggestions to help improve the clarity of the auto-reply and the Q&As, and recommend additional Q&As for development.
- Feedback can be provided directly to Stephanie Reid at [Stephanie.reid@canada.ca](mailto:Stephanie.reid@canada.ca).

### **Next Steps:**

- NNHPD will continue to explore options to improve the auto-reply function by updating the text to include:
  - Any feedback received from you or your members.
- We will continue to monitor the staffing changes made to date.
- We will hold another call in September, in order to provide you with an update after the summer, which should also align with the completion of our remaining staffing actions. A date will be set for this meeting in July 2019.

### **1. Web-based Product Licence Application**

Thank you for your support of the new web PLA. We have received a lot of great feedback from this initial version of the form. The feedback that we have received is summarized into two main categories:

- 1) Performance issues: Health Canada has updated the firewalls a couple of times in the past few months and each time there has been an issue. This has not been unique to the NNHPD with our program partners systems also being down. Although not unique to our program, we understand how frustrating it is for both our external stakeholders as well as our staff that have to use the systems to do their jobs. We are working with Shared Service Canada to help improve how systems are brought back following these types of global security updates.
- 2) Form content: The second major issue that has been raised is the content within the drop down list. For example, when you choose the MVM monograph, you are provided with all of the claims not just the ones that are pertinent to the ingredients within your product. Other issues are that constituents are not specific down to the MI that you have chosen, and when picking a product monograph, you get all the ingredients that are in all product monographs.

These issues are occurring because the NHPID which holds the information populating the form was not designed to work in this manner. In order to resolve these types of issues, we are currently building a new portion of the NHPID for the monographs. The next version of the form will point to this new database for monograph information. The next version of the form, will also validate that the information in compendial/class I submissions meets all of the monograph parameters.

We will once again be looking for stakeholder testing of the form the week of September 9<sup>th</sup>. NNHPD will be sending a call out to confirm that those that did testing on the Amendment Notification Form and the current version of the web PLA are still the appropriate people to ask for feedback.

[Auto Reply](#)

## [Product Classification](#)

## [Application Steps to Obtain a Site and Product License](#)

## [Status Update](#)

### [Cosmetics Alliance Submits Comments on U.S. Sunscreen Proposal](#)

On June 27, Cosmetics Alliance provided official comments to the U.S. Food and Drugs Administration (FDA) on their Sunscreen Drug Products for Over-the-Counter Human Use proposal. Our comments focused on the global nature of the personal care products industry and the highly integrated North American market. These realities were the impetus for the inclusion of the Cosmetics Annex in the Canada-US-Mexico Agreement (CUSMA).

CA included the Cosmetics Annex in our submission, with highlights, and requested that the US FDA meet the requirements of CUSMA and collaborate with their Canadian counterparts, Health Canada, to ensure the greatest possible regulatory alignment for sunscreens.

## **Environmental Updates**

### [Various Publications Under the Chemicals Management Plan](#)

#### Macrocyclic Lactones and Ketones, Ionones and Cyclohexanone Group

The [final screening assessment](#) for Macrocyclic Lactones and Ketones, Ionones and Cyclohexanone Group was published. It is concluded that the 11 substances in the Macrocyclic Lactones and Ketones, Ionones and Cyclohexanone Group do not meet any of the criteria set out in section 64 of CEPA. Please take the time to review the final screening assessment and let your CA Regulatory Team know if you have any questions.

#### Volatile Organic Compound Concentration Limits for Certain Products Regulations

Environment and Climate Change Canada (ECCC) posted the proposed [Volatile Organic Compounds](#) (VOCs) concentration limit for Certain products with a 60-day public comment period ending on September 6, 2019. As you may recall, Cosmetics Alliance has been working with ECCC over the past several years on this file and this has always been a hot topic at CA's Regulatory Workshops. The original proposal was published in 2008 and then later revised in 2013 to expand the product categories intended to be covered as well as to build in considerations for an averaging and trading program to facilitate compliance. In late March, CA met with officials from ECCC to discuss their intent to re-engage with their regulatory proposal to establish VOCs concentration limits for certain products including personal care products. This is a long-standing file with the proposal finally being released. The intent of these Proposed Regulations has remained static - to align with the definitions and category limits as outlined under the California Air Resources Board 2010 Consumer Products Regulations (CARB 2010).

We will be reviewing the proposed concentration limits to check for consistencies in definitions to ensure alignment in intent and spirit with CARB 2010 and engaging with our PCMA and RAIS committee for comments and feedback. If you would like to join a CA committee please email [regulatory@cosmeticsalliance.ca](mailto:regulatory@cosmeticsalliance.ca).

#### Draft Screening Assessment of Phosphoric Acid Derivatives Group

The [draft screening assessment](#) for phosphoric acid derivatives group was published for a 60-day public comment period ending on September 11, 2019. The Chemicals Management Plan conducted a screening assessment of three of six substances referred to collectively under the Chemicals Management Plan as the Phosphoric Acid Derivatives Group. These three substances were identified as priorities for assessment, as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns. The three other substances were determined to be of low concern through other approaches, and proposed decisions for these substances are provided in a separate report. It is therefore proposed to conclude that trixylyl phosphate, oleyl phosphate and the substance bearing CAS RN 119345-01-6 do not meet any of the criteria set out in section 64 of CEPA.

#### Chemicals Management Plan Science Committee

The [meeting record](#) for the July 2018 Chemicals Management Plan Science Committee meeting has been published. A committee report on advancing consideration of endocrine-disrupting chemicals under the *Canadian Environmental Protection Act, 1999* was also published.

#### Consultation for the Protection of Canadian Workers from Exposure to Chemicals

Health Canada is exploring ways to [enhance the protection of workers from exposure to chemicals](#) by integrating and leveraging the information, tools, and/or technical expertise of the Chemicals Management Plan and Health Canada's Workplace Hazardous Products Program.

In Canada, workplace health and safety is under the jurisdiction of the Federal [Health Canada (HC) and Employment and Social Development Canada (ESDC)], Provincial, and Territorial (FPT) governments. HC administers the Hazardous Products Act (HPA), Hazardous Materials Information Review Act (HMIRA), and their regulations, which impose hazard communication and labelling requirements on suppliers. ESDC and the provincial and territorial governments administer legislation concerning workplaces that fall within their respective mandates. HC also administers the Pest Control Products Act, which requires occupational exposure to be included in the risk assessment of pesticides, and requires product safety information (for example, regarding hazards and required personal protection equipment) be available where the product is used, including in the workplace. While the Canadian Environmental Protection Act, 1999 (CEPA 1999) is broad in scope, occupational exposure to chemicals of concern has not been included in CEPA 1999 risk assessments conducted within the context of the Government of Canada's Chemicals Management Plan.

HC has been working with FPT representatives from the Canadian Association of Administrators of Labour Legislation, Occupational Safety and Health Committee (CAALL-OSH), the Canadian WHMIS Coordinators Committee (CWC), the Intergovernmental WHMIS Coordinating Committee (IWCC) and the WHMIS Current Issues Committee, to identify potential opportunities in a future iteration of the Government of Canada's chemicals management program. The purpose of this consultation is to solicit feedback on the proposed elements and activities outlined in the report. This feedback will be considered by Health Canada when it contributes to the development of the next phase of the Government of Canada's chemicals management activities.

The report is being shared with Canadians for transparency, and to provide an opportunity to the public to provide additional information or considerations on the topic.

## Webinar on Zero Plastics Waste By Environment and Climate Change Canada

The Government of Canada is committed to being a global leader in reducing plastic waste and pollution. Over the past year, Canada has championed an international [Ocean Plastics Charter](#), worked with provinces and territories to launch a [Canada-wide Strategy on Zero Plastic Waste](#) and accompanying [action plan](#), and [announced major steps](#) to reduce plastic waste and pollution in Canada.

On July 30<sup>th</sup>, Environment and Climate Change Canada is offering a one-hour webinar, in English and in French, to update partners and other interested parties on federal activities and next steps, and to answer any key questions. The webinars will provide an overview of the Government of Canada's commitments and actions as well as the ongoing work with provinces and territories through the Canadian Council of Ministers of the Environment.

The webinars are open to businesses, governments, associations, not-for-profit organizations, and other interested groups. Please feel free to share this invitation with your members and partners. Webinars will include time for participant questions.

Please click on one of the links below to register.

- [July 30 from 12:00 – 1:00pm Eastern \(English\)](#)
- [July 30 from 2:00 – 3:00pm Eastern \(French\)](#)

If you have any questions regarding the webinar, please do not hesitate to contact us at [ec.plastiques-plastics.ec@canada.ca](mailto:ec.plastiques-plastics.ec@canada.ca).

## **Post-Consumer Waste Updates**

### Saskatchewan – New Household Hazardous Waste Products Stewardship Regulations In Force

On July 5, 2019 the Saskatchewan Ministry of Environment announced that the Saskatchewan Government has approved *The Household Hazardous Waste Products Stewardship Regulations*, requiring manufacturers and retailers (first sellers) of household hazardous waste (HHW) products to operate, or enter into an agreement with a person to operate on their behalf, a product stewardship program for household hazardous waste. Please refer to the [letter](#) and [Regulations](#) for more information on the program next steps. A clean copy of the regulations will also be posted online in the government publications section soon. Stakeholders with products meeting the criteria for the program should make plans for compliance by December 24, 2019.

### Ontario – New Blue Box Program Consultation and special advisor on recycling and plastic waste

Ontario has engaged David Lindsay as a Special Advisor on recycling and plastic waste. Mr. Lindsay will provide the Ministry of the Environment, Conservation and Parks a report later this summer on how to tackle plastic waste and litter, improve recycling, increase products that can go into the blue box and ensure producers are responsible for managing plastic and other packaging at end-of-life. In June, the ministry hosted a webinar with Mr. Lindsay that provided an overview of the mediation process and timelines, identified the key issues that will be



discussed and provided details on how stakeholders can provide input and be involved in the future regulatory development process.

#### Ontario MHSW Wind Up Plan – New Direction Letter and Extension

On July 2, 2019, the Minister of the Environment, Conservation and Parks issued a new direction to Stewardship Ontario for the wind up of the Municipal Hazardous or Special Waste (MHSW) Program. The Minister's [direction letter](#) to Stewardship Ontario extends the operation of the MHSW program for all designated materials except single-use batteries to June 30, 2021 instead of December 31, 2020. The program to manage single-use batteries will cease operation on June 30, 2020, as previously directed by the Minister. [Learn more about the Minister's direction and next steps for Stewardship Ontario](#). See also Stewardship Ontario's [MHSW Wind Up webpage](#). Please email [mhswwindup@stewardshipontario.ca](mailto:mhswwindup@stewardshipontario.ca) if you have any questions.

#### Ontario Wind Up of WEEE program - New Direction Letter and Extension

On July 2, 2019, the Minister of the Environment, Conservation and Parks issued new direction to Ontario Electronic Stewardship (OES) for the wind up of the Waste Electrical and Electronic Equipment (WEEE) Program. In his [direction letter](#), the Minister amended the timeline to wind up the waste diversion program for WEEE. The program will now cease operation on December 31, 2020 instead of June 30, 2020. The direction comes as a result of a report submitted by the Authority to the Minister in April 2019 that summarized public consultations held on options for the use of OES's surplus funds. The report identified stakeholder preference for the option to extend the operation of the WEEE program for an additional six months to draw down the surplus funds.

#### Ontario Resource Productivity and Recovery Authority - Highlights from AGM

On June 27, 2019 the Authority hosted its third annual general meeting. Stakeholders across various sectors were in attendance as we shared an update on key milestones from the past year. If you were unable to join us in-person or online, a recording is now available on RPRA's [YouTube channel](#).