

## Regulatory Essentials – October 14, 2020

### Cosmetics Alliance Update

Cosmetics Alliance Directory is Here!

Check out our [directory](#) which has tons of new features. Find company info faster and easier than ever before!

NHP Site Licensing Training Session 🏠 Sign up Today!

Natural Health Product Site Licensing

**Date:** Wednesday, October 28, 2020

**Time:** 2:00 pm - 3:30 pm

**Cost:** Member: \$250 Non-Member: \$395

#### **Learn and Understand:**

- Who requires a site licence?
- How to apply for a site licence
- How and when to renew your site licence
- How Health Canada processes applications and renewals

Each session will include exercises, a quiz, and a Q&A session.

Training Certificates are issued for your records to everyone successfully completing the quiz.

Individual logins are required for each participant to obtain a training certificate.

[Register](#)

### Health Update

DEL Bulletin LEPP No. 96 Electronic Issuance of Certificates of a Pharmaceutical Product and Good Manufacturing Practices Certificates

Health Canada (HC) recognizes the significant impact the COVID-19 pandemic has had on the global pharmaceutical product supply chain and strains it has put on both the pharmaceutical industry as well as international regulatory bodies.

To continue to meet the requirements of the voluntary agreement set out in the [WHO Certification scheme on the quality of pharmaceutical products moving in international commerce](#) during this pandemic, HC is launching a pilot to implement the electronic issuance of Certificates of a Pharmaceutical Product (CPP) and Good Manufacturing Practices (GMP) Certificates effective as of October 5<sup>th</sup>, 2020. Furthermore, as of today, Health Canada will no longer be sending electronically signed interim letters. This pilot is replacing the standard paper-based process in that no paper copies of electronically issued CPPs and GMP Certificates will be available.

Why is HC launching this pilot?

This pilot to implement the electronic issuance of CPPs and GMP Certificates (i.e. issue “e-CPPs” and “e-GMP Certificates”) will offer the following benefits:

- ✓ To continue to provide this critical service during the COVID-19 pandemic by using secure electronic signature features as recommended by the WHO,
- ✓ A “greener” process for receiving applications and issuing e-CPPs and e-GMP Certificates with the elimination of paper usage, and
- ✓ A more efficient and stream-lined process to issue e-CPPs and e-GMP Certificates and share with our international partners.

Stake Holder Instructions – [EN](#) / [FR](#)

FRM -0456 Fee Form for CPP & GMP – [EN](#) / [FR](#)

FRM-0455 GMP Certificate Application Form – [EN](#) / [FR](#)

FRM- 0454 CPP Application Form – [EN](#) / [FR](#)

Performance standards for NHP applications

The Natural and Non-prescription Health Products Directorate (NNHPD) would like to thank everyone who attended the *Performance standards for NHP applications* meeting that took place on Wednesday September 23rd, 2020. The webinar details are summarized below.

Performance Standards for NHP Applications – [EN](#) / [FR](#)

Additional packaging and labelling requirements for alcohol-based hand sanitizers packaged in beverage containers

A policy is being introduced to help reduce unintentional ingestion of alcohol-based sanitizers packaged in beverage containers. The high demand for hand sanitizer has led to significant shortages in both products and standard packaging. Packaging shortages have resulted in the use of unconventional types of containers such as beverage or food containers (for example, water and wine bottles).

The use of beverage containers for alcohol-based hand sanitizers may increase the risk of unintentional ingestion. Based on data from Canadian Poison Control Centres (PCCs), the number of reported incidents is increasing in 2020 and are much higher than in 2019.

The Natural and Non-Prescription Health Products Directorate (NNHPD) is implementing a policy requiring an alternative closure and an additional warning statement and symbol, to alcohol-based hand sanitizers packaged in a beverage container. These measures must be put in place no later than 8 weeks after this policy comes into effect, allowing existing stock to be used up. Hand sanitizers packaged in beverage containers and distributed after November 27, 2020, must have an appropriate closure along with the warning statement and graphic. Distribution in Canada of alcohol-based hand sanitizers packaged in beverage containers without these measures must stop after this date.

The [policy](#) is available on the Health Canada website and is in effect as of October 2, 2020.

## **Environmental Update**

### **Federal Government Announces First Targets in National Plastic Waste Reduction Initiative**

Federal Environment and Climate Change Minister Jonathon Wilkinson today announced the Canadian Government's first targets in the battle to reduce and eliminate unnecessary plastic waste. The first step will eliminate plastic straws, stir sticks, checkout bags, six-pack rings, cutlery, and food (take-out) containers by 2021 – all of which are single-use plastic items the Minister indicated aren't easily recycled and already have more environmentally-friendly alternatives.

The Minister's announcement, which follows on the Government's commitment in last month's Throne Speech to eliminate "single-use" plastics, also included the release of a 20 page discussion paper entitled "A Proposed Integrated Management Approach to Plastic Products" ([HERE](#)) and the 200 page "Final Report: Science Assessment of Plastic Pollution" ([HERE](#)). The former document begins a 60-day consultation period which closes December 9th.

In addition to the ban on the specific plastic items, the Government is proposing the development of an integrated plan to reduce/minimize various specific plastic products and/or packaging. The proposal – which is now out for public consultation features:

- Establishing a recycled content minimum
- Driving investment for diversion and collection (i.e. recycling infrastructure)
- Encouraging innovation to develop markets for recycled plastic

The Federal Government has also recognized the important role (and jurisdiction) of provinces and municipalities in developing a pan-Canadian approach in managing plastic waste and ensuring consistency across the country.

Several other items of interest identified in the Government's proposal include definition of Single Use as "designed to be thrown away after being used only once" and Categorizing Plastics into at least three categories:

- Convenience Items being those that are likely to be subject to a ban and would include the six items singled out as the initial target for elimination in 2021. (Also, on this list are disposable wipes – which may be important to our industry but are presently NOT considered to be subject to the proposed ban.)
- Packaging Items (including plastic bags, subject to the Ban) and the following other items (which will be subject to the integrated management plan) including "primary packaging" (i.e. food wrappers, retail product packaging, beverage and shampoo bottles), and "secondary or short-lived packaging" (i.e. fruit and vegetable bags, containers, sanitary packaging and sterile items like syringes)
- Essential Items that will not be subject to any proposed action at the current time (i.e. masks, latex gloves the dental and medical field, sterile packaging)

### CA Analysis of Effects on Cosmetic & Personal Care Product Industry

Following a brief analysis of the documents released today, this will potentially impact our industry with respect to:

- Cotton swab sticks
- Flushable and disposable wipes

- Disposable personal care items
- Plastic packaging

CA Canada will review these publications and engage our membership accordingly as this is a development we have been anticipating and preparing for. We will also continue our engagement with other trade associations and fully engaged in the Government's consultation process. CA will also review the science assessment to see how this document can be leveraged in our advocacy moving forward.

A copy the Minister's Announcement is available [Here](#).

CA will continue to keep you updated on this issue as it develops as it has the potential to have significant impacts on your business.

Publication of the draft Screening Assessment and the Risk Management Scope for the Other Polymers Group

On Friday October 2, 2020 Environment and Climate Change Canada published the Draft Screening Assessment of Other Polymers Group. Four substances were part of the screening assessment:

<b>CAS RN</b>	<b>Domestic Substances List name</b>	<b>Acronyms</b>
55818-57-0	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with (chloromethyl)oxirane, 2-propenoate	DGEBA-DA resin
32289-58-0	Poly(iminocarbonimidoyliminocarbonimidoylimino-1,6-hexanediyl), hydrochloride	PHMB
27083-27-8 <sup>a</sup>	Guanidine, N,N''-1,6-hexanediylbis[N'-cyano-, polymer with 1,6-hexanediamine, hydrochloride	
67762-15-6	Soybean oil, polymer with maleic anhydride, pentaerythritol and phthalic anhydride	Soya alkyd resin

125826-44-0	Hexanedioic acid, polymer with 2,2-dimethyl-1,3-propanediol, 1,6-hexanediol, hydrazine, 3-hydroxy-2-(hydroxymethyl)-2-methylpropanoic acid and 1,1'-methylenebis[4-isocyanatocyclohexane], compd. with <i>N,N</i> -diethylethanamine	Polyurethane-33
-------------	--	-----------------

<sup>a</sup> This CAS RN was previously assessed under the second phase of polymer rapid screening, but it is being reassessed as it is equivalent to CAS RN 32289-58-0.

A Risk Management Scope has been published along with the Draft Screening Assessment since one out of the four substances above, PHMB, was proposed to maybe harmful to human health and meets the criteria under CEPA. PHMB is used as a antimicrobial preservative in cosmetics and pharmaceuticals and is listed on the NHPID as a non-medicinal ingredient. It has been reported that the substance is not manufactured in Canada, but that between 100 and 1000 kilograms of PHMB were imported into Canada in 2014. Direct exposure (oral, dermal, inhalation) of the general population to PHMB is expected.

Cosmetics Alliance will be reviewing the Draft Screening Assessment and its corresponding Risk Management Scope. We will be engaging with this committee and members as we look to understand how we will be pursuing any follow-up. To support these efforts, we would appreciate understanding from this committee whether or not there is any interest in this substance as there are 148 VCRP hits and 282 cosmetic notifications since 2015.

Please take some time to review the notices below and let us know if you have any questions/concerns or feedback.

Other Polymers Group:

- [Draft Screening Assessment](#)
- [Risk Management Scope](#)
- [Canada Gazette Notice](#)

#### Recent Developments for Triclosan and Triclocarban

##### [P2 Planning Notice for Triclosan:](#)

The final P2 Planning Notice for Triclosan has been released today by Environment and Climate Change Canada (ECCC). Health Canada and ECCC published a joint scientific assessment of triclosan in November 2016. A proposed Notice was published on November 24, 2018 for a 60-day comment period. The assessment concluded that potential for harm exists from exposure to triclosan in aquatic ecosystems. The notice applies to manufacturers and importers of Cosmetics, Drugs and NHPs who manufacture or import products with Triclosan of 100 kg or more. There are different considerations in the Notice depending on if you have been historically

producing products containing Triclosan or if your looking into bringing products containing Triclosan for the first time. The two scenarios are highlighted below:

For companies with historical activity with Triclosan (meet Notice threshold in 2020):

- Targets 30% reduction from use/import volumes from base year (any year prior to 2020 but no earlier than 2011)
  - any reductions realized in the past (going back to 2011) can be considered

After the Notice comes into force notifiers have 12 months to prepare a plan and 30 days following the 12 months the notifier must issue a declaration of planning by October/November 2021 within 30 days of the 12-month period. The plan must be in place for 2 years following the declaration (2023).

For companies looking to introduce new product in the market (meet Notice threshold in 2021 and beyond):

- Target 95% reduction
- Have 12 months to prepare a plan
- Same declaration logistics as historical notifiers (please see above)
  - Plan must be in place 1 year following declaration

This final notice was supposed to be published March/April but was delayed because of COVID-19.

Please note that there are provisions for a one-time extension if needed, which is rationale based (COVID-19 and economic reasons can be used as a rationale). If you have reduced the use or import of triclosan prior to [publication of the notice](#) and are no longer subject, ECCC invites you to submit a [Notification of Non-Engagement form](#) to the email address to [ec.products-products.ec@canada.ca](mailto:ec.products-products.ec@canada.ca).

Draft Screening Assessment of Triclocarban:

Environment and Climate Change Canada will be releasing the [Draft Screening Assessment for Triclocarban](#) on Saturday, October 10, 2020. This is an interesting development as we were expecting it to reflect a similar finding to Triclosan especially reflecting the environmental conclusions for Triclosan. It is concluded that Triclocarban does not meet any of the environmental or human health concerns and is concluded to be not CEPA toxic. While exposure of the general population and the environment to triclocarban is not of concern at current levels, the substance is associated with effects of concern. Therefore, there may be concern if exposure were to increase. Follow-up activities to track changes in exposure or commercial use patterns are under consideration. Cosmetics Alliance is aware that this substance is of high interest in the NGO community.

The draft Screening Assessment will be subject to a 60-day public comment period and will be available on the [Chemical Substances website](#).

Please let us know if you have any comments or concerns however we do not anticipate any concerns as this a positive conclusion for Triclocarban.

## **Post-Consumer Waste Update**

### **RPRAs Consultation on the Proposed Blue Box Program Transition Plan**

Thank you to all those who participated in Stewardship Ontario's Blue Box Program Transition Plan consultation process throughout the spring and summer.

After approval from the Board of Directors, Stewardship Ontario submitted its proposed Transition Plan to the Resource Productivity and Recovery Authority (RPRAs).

RPRAs has posted the Transition Plan and its consultation information [here](#). Consultations will start the week of October 12, with feedback due by November 10.

The Minister anticipates RPRAs will approve the plan no later than December 31, 2020

### **2020 Registry fees for Tires, Batteries, and Electrical and Electronic Equipment posted**

The Authority has posted the 2020 Registry fees for tires, batteries and EEE. These are fees that registrants pay to the Authority to cover the Authority's costs related to building and operating the Registry, and compliance and enforcement activities. [Learn more and view the fee schedule](#).

All feedback received was considered during the consultation process when finalizing the fees. Stakeholder feedback has been summarized in a consultation report, which you can be found on their [website](#), as well as more information on the consultation process.

### **October 21 Annual Steward Meeting – register now**

The 2020 Annual Steward Meeting for packaging and paper stewards is scheduled for Wednesday, October 21 at 1 p.m. ET. The meeting will be held via Zoom this year. The Report to Stewards that includes 2021 fee rates will be distributed in advance. [Click here](#) to register.

### **Voluntary Steward Deadline – December 1**

New voluntary stewards who want to start reporting in 2021 need to submit a Voluntary Steward Agreement (VSA) for each packaging and paper program by December 1, 2020. Existing voluntary stewards who wish to cancel their VSA and not report in 2021 are reminded to notify the program(s) by December 1, 2020. See the [Voluntary Steward Policy](#) for more information.

### **Zero Waste Conference**

CSSA is a proud partner of the Zero Waste Conference taking place on November 13, 2020. The virtual event features a range of speakers sharing insights on how circular solutions can help move us to a resilient and prosperous future. Further information and registration is available on the [conference website](#)