

Regulatory Essentials – June 9, 2021

Cosmetics Alliance Updates

Our First Ever Virtual Regulatory Workshop was a Success!

Cosmetics Alliance hosted its first ever Virtual Regulatory Workshop on June 1 & 2, 2021 with over 100 people in attendance. Attendees were provided updates from Health Canada's directorates CHPSD, NNHPD & HPCD (ROEB). Our first ever DG Panel with Natalie Page (NNHPD), Linsey Hollett (HPCD) and Roger Charland (CHPSD) and Darren Praznik (CAC) was the highlight of the event. The three DGs reflected on the past year and how they can leverage what they learned during the pandemic into the SCF. 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.

Upcoming Executive Briefing & Networking Event with Covanta Environmental Solutions

Topic - Waste-to-Energy - What you Need to Know for Your Business

Date: Thursday, June 10, 2021

Location: Virtual Event (bring your lunch!)

Agenda:

12:00 pm - 12:15 pm: Darren Introduces speakers

12:15 pm - 12:45 pm: Speakers & Updates

12:45 pm - 1:00 pm: Discussion & Networking

Hosts: Edward Vago, Director Business Development & Rachael Graziotto, Analyst, Sales and Operations

Learn about:

- Why is Covanta relevant to Cosmetic Alliance/ Who is Covanta?
- Waste-to-Energy: Good or Evil?
- What is circular economy?
- Best practices for waste management

CA President, Darren Praznik will provide an update on:

- The Self Care Products Framework and the opportunities for you business
- The modernization of Canadian Environmental Protection Act (CEPA)
- Reducing the risk of Covid-19 in manufacturing workplaces and in person retail and more!

[Register](#)

Interactive Training Session - The Notorious Confusables - Back by Demand!

Date: June 22, 2021

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

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

Format: Webinar

These often-confusing terms are used in the cosmetic, natural health product and drug industries.

- Where are you in this diagram?
- Are you who you think you are?
- Do you know where vendors fit?

These terms are very important when reading through the cosmetic, drug and NHP regulations and guidance documents.

Objectives

- Become confident in differentiating these terms to ensure your compliance obligations are clear
- Learn what these terms mean and how to apply their definitions
- Compare and contrast the differences in these terms in each of the regulations

This interactive training session will teach you the differences and the importance of these terms and answer often-encountered questions.

The 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.

Testimonial

"A big thanks for your session yesterday on the Notorious Confusables. I did in fact not realize all the stuff that is in my head, that once put to paper, and for any newcomers, is very complex indeed. The quiz in fact gave me a lot of pause, but managed through successfully with a lingering headache, LOL! Definitely a slide deck I am going to retain for future reference."

[Register](#)

Health Updates

Upcoming NNHPD Performance Standards for NHP Applications Call

The Natural & Non-prescription Health Products Directorate (NNHPD) will be having their next Performance Standards for NHP Applications update call on **June 10, 2021, from 2:00 – 3:00 p.m. EDT.**

Agenda:

- Workload update: Product and Site licence applications (30 minutes)
- Update on Covid Site Licenses (15 minutes)
- Systems update (15 minutes)

Meeting details:

Join Zoom Meeting:

<https://ca01web.zoom.us/j/66100608285>

Meeting ID: 661 0060 8285

Passcode: 545377

Invitation to Health Canada's Webinar on the Implementation of the Plain Language Labelling (PLL) Requirements

Health Canada is mindful that it has been a particularly challenging time for all since the start of the COVID-19 pandemic, given that it is not business as usual. In this context, and in an effort to keep the communication lines open and clear, Health Canada would like to provide information to key interested stakeholders on the path forward regarding the implementation of the PLL initiative for OTCs, which remains a priority for Health Canada. This webinar will aim to reiterate our communication on this topic over summer 2020, and summarized in the attached communication issued November 30, 2020.

The Natural and Non-Prescription Health Products Directorate (NNHPD) and the Health Product Compliance Directorate (HPCD) are organizing a webinar on **Friday, June 11, 2021 from 11:00 to 12:00 EDT** to discuss this matter. Please see agenda below.

Join Zoom Meeting

<https://ca01web.zoom.us/j/66353071293>

Meeting ID: 663 5307 1293

Passcode: 987164

[Meeting Agenda](#)

HC QA PLL for NPD – [EN/FR](#)

Letter to OTC DIN Holders – [EN/FR](#)

CA's Self-Care Framework (SCF) Dedicated Session– Join the Discussion!

Cosmetics Alliance will be hosting a dedicated session on the Self-care Framework specifically on Self-Care Framework – Phase I - Improved Labelling of NHPs with our Product Compliance & Market Access (PCMA) and Facility Compliance & Manufacturing (FCM) committees. This session is scheduled for **June 17, 2021 from 1 p.m. to 4 p.m. EDT** and will be virtual through Microsoft Teams. If you are not part of these committees and would like to be part of the conversation to help shape the SCF elements to your business advantage, please email regulatory@cosmeticsalliance.ca to join a committee. Below is a description of all CA's committees. Please note these are working committees so please come prepared to be part of the discussion.

[Committee Descriptions](#)

Annual Drug Notification Packages – 2021

Health Canada's Office of Submissions and Intellectual Property (OSIP) has distributed this year's annual drug notification packages via email to all DIN Holder company contacts.

Highlights of this year's package include:

- Although the regulatory deadline for returning the notification is September 30, Health Canada is requesting the information be returned by July 30, 2021. Cooperation is being requested in meeting this timeline.
- An e-billing program has been established and enrolment is requested, to streamline the invoicing process.
- Business numbers issued from the Canadian Revenue Agency (CRA) to reduce red tape and provide easier, faster, and smarter service delivery from all Government of Canada business services.
- Routine identifiers are being requested for Web Trader and AS2 users within the Common Electronic Submissions Gateway (CESG)

Please see below the ADNF package and a blank ANDF form for more specifics and instructions.

Annual Package 2021 – [EN/FR](#)

[Annual Drug Notification](#)

Extension to provide confirmatory information on risk assessments for nitrosamine impurities

Please find below a letter outlining revised timelines to complete the Annexes in connection to Health Canada's letter of April 14, 2021, following up on the completion of nitrosamine risk assessments. Also linked below are answers to new questions to help guide completion of the Annexes.

Please note that this communication is intended for Market Authorization Holders (MAHs) of human prescription and non-prescription pharmaceutical products with a Drug Identification Number (DIN) that contain chemically-synthesized active pharmaceutical ingredients (APIs). It is not intended for MAHs of natural health products.

Extension for RA Follow-up – [EN/FR](#)

QA on RA Follow-up – [EN/FR](#)

Stakeholder Consultation - Modernizing Health Canada's Clinical Trials Framework

Health Canada will be hosting a webinar on June 22 to provide information regarding the Clinical Trials Modernization Initiative as it relates to clinical trials for health products.

Health Canada launched a [consultation paper](#) and an accompanying [questionnaire](#) for the [Clinical Trials Regulatory Modernization Initiative](#) on May 20, 2021. The consultation paper introduces several wide-ranging proposals for transforming Canada's regulatory framework for clinical trials related to human drugs, medical devices, and natural health products. The proposals are intended to meet several key policy objectives, including the provision of proportional risk-based oversight; new regulatory agilities over the lifecycle of the trial; greater transparency through registration and public disclosure of results; and a modernized and expanded compliance and enforcement regime.

HOW TO JOIN:

Use the following link or other methods to join the session:

<https://canada.webex.com/canada/j.php?MTID=mebe032dbc4b373ab1a26c324dc4e008e>

Password: 7g7uKmSXf6\$

<https://canada.webex.com/>

Meeting number (access code): 173 874 4698

Meeting Password: 7g7uKmSXf6\$

Tap to join from a mobile device (attendees only)

[1-855-288-0982](tel:1-855-288-0982), [1738744698##](tel:1738744698) Canada Toll Free

[+1-438-797-4001](tel:+14387974001), [1738744698##](tel:+14387974001) Canada (Montreal)

Join by phone (optional)

1-855-288-0982 Canada Toll Free

+1-438-797-4001 Canada (Montreal)

+1-416-915-6530 Canada (Toronto)

+1-604-449-3026 Canada (Vancouver)

Access code: 173 874 4698

[Other Canadian and Toll-free numbers](#) | [Toll-free calling restrictions](#)

Environmental Updates

CMP Publications Plan for July to September 2021

The Chemicals Management Plan is sharing the following Publications Plan to inform stakeholders of publications from July to September 2021. The program anticipates sharing the Publications Plan for October to December 2021 by fall 2021.

Publications targeted for July to September
Approach for a Subset of Organic and Inorganic Substances Prioritized under the Chemicals Management Plan ^c
Benzoxazole, 2,2'-(1,4-naphthalenediyl)bis- FSAR ^b
Caprolactum Caprolactam DSAR ^a
Corn, Steep Liquor FSAR ^b
Lotus Corniculatus, extract FSAR ^b
Nonane, 2,2,4,4,6,8,8-heptamethyl-FSAR ^b
Triazines and ckFSAR ^b

^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 policy approach documents.

Note: Group names are not final and may change

To increase transparency with its stakeholders, the program is also published the following list of publications that the program plans to publish throughout this fiscal year. Highlighted in yellow are of relevance to personal care products/cosmetics.

Publications targeted for October 2021 to March 2022
4,7-Methano-1H-indene, 3a,4,7,7a-tetrahydro- FSAR ^b
A Subset of Inorganic Substances Identified as Being of Low Concern Using the Ecological Risk Classification of Inorganic Substances and Biomonitoring or Rapid Screen Science Approaches ^c
Acids & Bases DSAR ^a
Additional Risk Characterization Document and Addendum to the Risk Management Scope for 2-furanmethanol ^d
Alcohols DSAR ^a
Alkyl Halides DSAR ^a
Ecological risk classification of inorganic substances (ERC-II) SciAD ^c
Esters DSAR ^a
Flame Retardants DSAR ^a
Framework for the Risk Assessment of Manufactured Nanomaterials under the <i>Canadian Environmental Protection Act, 1999</i> ^c
Phenol, methylstyrenated DSAR ^a
Poly(alkoxylates/ethers) FSAR ^b
Propane, 1-nitro- FSAR ^b
Resins & Rosins FSAR ^b
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica FSAR ^b
Sodium Cyclamate and Cyclohexylamine FSAR ^b
Sulfurized Isobutylene FSAR ^b

^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 policy approach documents.

^d The DSAR for furan compounds was originally published on September 1, 2018. Additional human health exposure information has since been identified or generated; therefore an additional risk characterization document for 2-furanmethanol (furfuryl alcohol) and an addendum to the risk management scope will be published.

Note: Group names are not final and may change

Post-Consumer Updates

Updates from The Canadian Stewardship Alliance

Reporting deadline reminder

Packaging and paper stewards are reminded that 2021 reports of 2020 data were due to be submitted to the [WeRecycle Portal](#) by **May 31, 2021**. A wide range of tools and information to assist reporting, including the Ready to Report Webinars, are available on the [2021 Reporting Resources](#) webpage. National Steward Services is available to assist with any questions and will be contacting some stewards to validate report data.

Annual Steward Meeting – save the date

The 2021 Annual Steward Meeting is scheduled for Wednesday, **October 27**, at 1 pm ET. The meeting will be a webinar event again this year. Invitations and details will be distributed in late summer.

Final Blue Box Regulation issued

The Ontario government has issued the final [Blue Box Regulation](#) under the Resource Recovery and Circular Economy Act. Stewardship Ontario is reviewing the Regulation to determine what changes may be required to the Blue Box Transition Plan approved by the Resource Productivity and Recovery Authority (RPRRA). Further information about the Blue Box Regulation and the program transition is available on the [RPRRA website](#).

New Executive Director appointed

The Stewardship Ontario Board of Directors recently [announced the appointment](#) of Lyle Clarke as the organization's new Executive Director. Lyle succeeds Gemma Zecchini, who resigns after overseeing the successful wind-up plans for the Blue Box and the MHSW programs. Lyle has extensive experience with recycling in Ontario and his new role will be combined with his previous Program Operations Officer responsibilities.

MHSW Program extension

Following the April 29 [direction letter](#) from the Ontario government extending the MHSW Program by three months to September 30, 2021, Stewardship Ontario held a [consultation webinar](#) to present the proposed amendments to the wind up plan. The addendum to the MHSW Wind Up Plan was submitted on May 28 and is available on the [RPRRA website](#), with approval anticipated by June 30.