Regulatory Essentials – February 23, 2022

Cosmetics Alliance's Environmental Symposium - Engaging Minds, Building the Future

Please join us in our first ever virtual Environmental Symposium on March 23rd from 9 a.m. to 12 p.m. EST. Hear from Environment and Climate Change Canada (ECCC) on the topics that matter for your business:

- Overview of New Volatile Organic Compounds (VOCs) in Certain Consumer Products Regulations
- Upcoming Priorities under the Chemicals Management Plan
- Early Considerations to Address Recycled Content Proposals & Plastic Materials

This symposium will include a breakout session to further build upon the discussions and connect with your industry colleagues on these critical topics.

Date: March 23, 2022
Time: 9 a.m. to 12 p.m. EST
Location: Virtual
Cost: $175

Agenda

Register

Health Updates

DEL Bulletin LEPP No.127: Updates to the Generic Email Accounts and Contact Information

Health Canada migrated to the M365 email service in August 2021, which had a slight impact on the generic email accounts that was used to communicate with the department.

Specifically, all email accounts have transitioned from the "@canada.ca" format to the "@hc-sc.gc.ca" format. Please note that all emails sent to the "@canada.ca" addresses are still being delivered successfully, however Health Canada's auto-reply messages from the generic email accounts are not being sent.

To ensure you receive all the appropriate auto-reply messages, which confirm receipt of your email or application by Health Canada and may contain pertinent information/key updates, Health Canada asks you please send your correspondences to the following generic account's addresses:

For submitting questions related to:

Active Pharmaceutical Ingredients	api.questions-ipa@hc-sc.gc.ca
Annual Licence Review	del.alr-eal.lepp@hc-sc.gc.ca
Certificates of Pharmaceutical Products	cpp_questions@hc-sc.gc.ca
Compliance and enforcement activities for health products	hpce-cpsal@hc-sc.gc.ca
Drug Shortages	drug.shortages-penurie.de.medicament@hc-sc.gc.ca
Exceptional Importation and Sale related to drug shortages	drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca
Foreign Sites	foreign.site-etranger@hc-sc.gc.ca
Good Manufacturing Practices (GMP) requirements	drug.gmp.questions-bpf.medicaments@hc-sc.gc.ca
Good Pharmacovigilance Practice (GVP) requirements	gvp-bpv@hc-sc.gc.ca
Import and export of health products	hpbcp-pcpsf@hc-sc.gc.ca
Licensing, Drug Establishment License (DEL) amendment, or general inquiries about licensing	del.questions-leppp@hc-sc.gc.ca
Natural Health Products Good Manufacturing Practices Inspections	hpcrm.nhpinspection-inspectionpsn.cpsgr@hc-sc.gc.ca
Recall of drugs or natural health products	
• New Brunswick, Newfoundland and Labrador, Nova Scotia, Prince Edward Island, Québec	HC.qoc-coq.SC@hc-sc.gc.ca
• Ontario	HC.insponoc-coon.SC@hc-sc.gc.ca
• Manitoba, Saskatchewan, Alberta, British Columbia, Yukon, Northwest Territories, Nunavut	insp_woc-coo@hc-sc.gc.ca

For submitting:

Comments during consultation period	hpil-consultation-ipsop@hc-sc.gc.ca
DEL amendment application/FRM-0033	el.applications-le@hc-sc.gc.ca
Health Product Consumer or Trade Complaints	Health Product Complaint Form (FRM-0317) or ctu-uct@hc-sc.gc.ca

Health Canada Posted Good Manufacturing Practices for Active Pharmaceutical Ingredients (GUI-0104)

On February 10, 2022, Health Canada posted *Good manufacturing practices for active pharmaceutical ingredients (GUI-0104)* to the Health Canada website as described in DEL Bulletin

No. 125. The Health Product Compliance Directorate has pre-recorded a webinar to outline key changes to Health Canada's guidelines for *Good manufacturing practices for active pharmaceutical ingredients (GUI-0104)* and to provide you with contact information should you have any questions. This format has been chosen to provide flexibility in scheduling, and to allow you to proceed through the presentation at your own pace. The webinar is available at the link below.

GUI-0104 Overview of Changes: https://gccollab.ca/file/view/11569113/gui-0104-summary-of-changes-external-webinar-en-mp4

Access to Webinar

To access the webinars, you will need to register with GC Collab if you are not already registered. To register to GC Collab, please provide the e-mail addresses to del.questions-leppp@hc-sc.gc.ca and you will receive an invite. Once your account is created, you can access the HPIL group page via https://gccollab.ca/groups/about/804947 and access the GUI-0104 Webinar in the **Files** section.

If you have any questions, please email api.questions-ipa@hc-sc.gc.ca.

Reminder to Register for GC Collab Access

To access the DEL Bulletins and pre-recorded webinars, you will need to register with GC Collab if you are not already registered. To register to GC Collab, please provide the e-mail addresses to del.questions-leppp@hc-sc.gc.ca. Once your account is created, you can access the HPIL group page via https://gccollab.ca/groups/about/804947 and access the DEL Bulletins and any webinars

If you have any questions, please email api.questions-ipa@hc-sc.gc.ca.

Cosmetic Notification Form Update

The Consumer & Hazardous Products Safety Directorate (CHPSD) has officially started the automatic processing of the Cosmetic Notification Form (CNF) on February 7th, 2022. This was first revealed by CHPSD at CA's Virtual Winter Regulatory Workshop back in December. CNFs that do not contain prohibited or restricted ingredients will be automatically processed without an inspector reviewing the form. Procedurally, this automation step will ensure more prompt confirmation of notifications for products without prohibited or restricted ingredients – this is a positive first step towards improved timeliness of notification status to stakeholders. All other cosmetic notifications will continue to be processed by a Health Canada Officer. Please note there

is no change to the actual Cosmetic Notification Form. Notifications that are automatically processed will receive an automated email from hc.donotreplyradar-nepasrepondre.sc@hc-sc.gc.ca, rather than a Health Canada Officer, with an assigned Cosmetic Number.

We encourage you to provide us with any feedback **(positive or negative)** on your initial interactions with the system, so that we can collate/share our membership's collective engagement with the new system to CHPSD. Please also share any automated messages that you may receive when the product is assessed by the system but passed along to an inspector for review for any reason. Please provide us any feedback/concerns by March 22, 2022. In the interim, if you have any questions or concerns, please email regulatory@cosmeticsalliance.ca.

Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs) – Summary

Health Canada has updated the Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs) to introduce process changes related to the Regulatory Enrolment Process (REP), and increase clarity regarding the other existing processes. If you have any questions regarding the update, please email regulatory@cosmeticsalliance.ca.

Extension: Survey on Health Canada's Pilot NHP GMP Inspection Program

In February 2021, the Health Products Compliance Directorate (HPCD) in partnership with the Natural and Non-prescription Health Products Directorate (NNHPD) launched a pilot NHP GMP Inspection Program with a plan to inspect 36 Site Licence Holders (18 importers and 18 manufacturers). The pilot is expected to conclude at the end of March 2022 and the results will be posted in the coming months.

The Department is collecting feedback directly from stakeholders inspected during the pilot about their inspection experiences (survey below). This feedback is important, as it will help The Department understand what went well, determine whether changes to processes may be necessary and identify future initiatives for collaborating with stakeholders.

Please take a few moments to complete the survey. It will close in two weeks on **March 10, 2022**.

As a reminder, if you were inspected as part of the NHP Pilot GMP program we would like to year from you to share your experiences and to help inform next steps with Health Canada.

Please reach out to us at regulatory@cosmeticsalliance.ca if you are interested.

The survey can be accessed in English or French by clicking this link:

EN:
https://ca1se.voxco.com/SE/?st=15h1WlL2SWaMIs7h4p1vCeUjo9muoWNC6a2pEfY7Bnc%3D&lang=en

FR:
https://ca1se.voxco.com/SE/?st=15h1WlL2SWaMIs7h4p1vCeUjo9muoWNC6a2pEfY7Bnc%3D&lang=fr

Notification to Stakeholders – EN/FR

Survey External Stakeholders – EN/FR

Environmental Updates

An Update on the Proposed Amendments to the Food and Drugs Act for the Assessment and Management of Environmental Risk from Drugs

On April 13, 2021, the previous Government of Canada introduced Bill C-28 (*Strengthening Environmental Protection for a Healthier Canada Act)* in the House of Commons, announcing their intent to modernize the *Canadian Environmental Protection Act, 1999* (CEPA) and strengthen the FDA to include environmental risk assessment and risk management authorities. However, as Bill C-28 did not reach Royal Assent prior to the fall 2021 Canadian federal election, the proposed legislative amendments to CEPA and the FDA were reintroduced, unchanged, to Parliament, on February 9, 2022, as Bill S-5.

The proposed amendments to the FDA will provide the Minister of Health with:

- The ability to create regulations to assess and manage environmental risks from drugs, and prohibit the sale of a drug unless its ingredients have been assessed under these regulations; and
- A suite of environmental risk management tools under the Act. The suite of authorities will provide the ability to manage environmental risks from drugs, and they build upon the previously established authorities in place for health and safety purposes (such as mandatory recalls, fines and penalties).

The proposed amendments will bring the Government one-step closer in the development of a single-window regulatory framework that will bring the notification, assessment, and risk management of drug products and new drug ingredients under one Minister and Act.

As Health Canada continues its work to advance the development of an environmental risk assessment and risk management regulatory framework for drugs under the FDA, stakeholders are a encouraged to consult Health Canada's Forward Regulatory Plan, which provides additional

information on upcoming regulatory initiatives as they become available. The question-and-answer document is available below for more information on this initiative.

Q&A – EN/FR

Recycled content for Plastic Manufactured Items

Over the past couple of weeks, a couple of notable developments have arisen regarding Canada's Environmental Protection Act, which is the legislative backbone of Canada's world-leading Chemicals Management Plan (CMP) and Environment and Climate Change Canada's (ECCC) evolving approach to managing plastics and plastic waste (recycled content). A brief overview of these developments is outlined below, as preliminary background and context, in advance of the focused topic (joint committee meeting) that we will be organizing to delve into further detail on both of these fronts [note: a doodle poll seeking availability for this meeting was sent earlier today].

You will have also received an invitation to register for our upcoming Virtual Environmental Symposium that is scheduled for March 23rd, where we have invited ECCC to address and elaborate in further detail their proposed approach to address recycled content in "plastic manufactured articles" (i.e., plastic packaging) as summarized, below.

Needless to say, things are about to get very busy in the 'environmental space' – so do stay tuned!

BILL S-5 – CEPA Modernization Tabled in the Senate

Further to our communique from February 8, 2022, Bill S-5 *"Strengthening Environmental Protection for a Healthier Canada Act"* was recently tabled in the Senate. This Bill effectively is unchanged from that tabled this past Spring 2021 (Bill C-28) and consequently is a re-introduction of the Proposed Amendments to Modernize the Canadian Environmental Protection Act (CEPA) that was advanced in the previous Parliamentary Session.

The fact that this Bill is intact from that tabled last Spring is a positive development, as collectively, CA Canada, and by in large, the majority of industry sectors with interest in CEPA were largely supportive of the modernization approach as outlined. On this basis, CA Canada will look to support the advancement of the Bill through the legislative process as drafted, with minimal disruption and/or significant amendment. In this regard, we will be coordinating a GR outreach strategy and advocacy plan, engaging as necessary with relevant MPs (across all parties) and Senators (including key Committee representatives) to provide supporting perspectives that will look to preserve the balance of the Bill, as presently drafted. In this regard, we may be calling upon members with MPs in key jurisdictions to support these efforts, moving forward.

With the Bill S-5 being effectively unchanged from that tabled last spring, the key elements of the Bill are consistent with those we previously summarized, namely:

Overall, the Bill continues to maintain a risk-based approach, which is a foundational underpinning of Canada's chemicals and environmental management strategy. Many of the elements reinforce principles that already exist in the current statute or were anticipated as they build on existing provisions, including:

- Vulnerable populations
- Cumulative effects
- Alternative assessments
- Precautionary principle
- etc.

On the surface, there are some potentially positive elements that are featured, including:

- Enabling mechanism for legitimizing the Revised In-Commerce List (R-ICL)
- Recognition of alternatives to animal testing methods and new assessment methods
- Enhancement of the recognition of the principles of 'Best Placed Act'
- Possibility for the re-naming of Schedule 1 (opportunity to move away from the term 'toxics')

Finally, there are a few new developments that were introduced that we will need to take some time to better understand, including:

- Introduction of a 'Watch List' and how this will be implemented
- Integration of environmental risk assessment provisions for "drugs", to ensure that corresponding amendments to the F&DA will be duly focused on prescription drug actives as an extension of New Drug Submission pre-market assessments; with the current approach to environmental assessments of 'low risk' active and non-medicinal ingredients being retained within the Self-Care Framework
- Consumer information and labelling and if it is risk-based and appropriately balanced

CA Canada has already reached out to other industry sectors and will of course be collaborating with the CEPA ICG as we work through the technical elements of the Bill. We will also be outreaching to our colleagues at PCPC, IBA and US FCA to review and discuss these developments, and to coordinate engagement accordingly.

ECCC Publishes 'Technical Paper' in Support of Their Proposed Approach towards Establishing a Minimum RECYCLED CONTENT Limit for Plastic Packaging in Consumer Goods Packaging and Components

This past weekend February 12, 2022, the Government of Canada also published a Notice in Canada Gazette 1 outlining the Technical Considerations that they are looking for input on in order to develop a proposed new regulation to designate a minimum recycled content limit that would apply to "certain plastic manufactured articles" that extends to plastics in consumer goods packaging and their respective plastic components (i.e., caps and closures).

This paper presents some of the early thinking that ECCC is contemplating in relation to these future policy activities, and most importantly provides some insights as to the possible policy direction and data gaps that they are looking to address/better understand as these proposed regulations take shape.

We are pleased that in line with the commentary that CA Canada (and other industry stakeholders) submitted in response to the Proposed Integrated Management Approach to Plastic Products Discussion Paper that ECCC published in 2020, that the Government appears to be contemplating a product specific, sectoral approach towards the designation of possible proposed limit and are therefore looking to embark on a consultative process (of which this is the first step) to identify challenges and determine feasibility of a multitude of approaches, sectorally, recognize that a 'one-size fits all' approach is unlikely to be effective. In this regard, ECCC has already outreached to CA Canada to set up a series of follow-up discussions to further elucidate the cosmetic/personal care perspective and what our sector would like to address in relation to the outlined regulatory objectives. Therefore, this is an important first opportunity to initiate a sectoral dialogue to:

1. Address the feasibility of the aspiration 50% recycled content minimum by 2030 (and/or provide alternative targets/approaches) that could facilitate our industry's sectoral engagement in relation to these environmental objectives
2. Identify and discuss possible technical, supply-chain, economic challenges that may need to be addressed to ensure a meaningful mitigation contribution to the overall aspirational environmental objective
3. Seek input on possible innovations and/or engagement opportunities to address challenges and/or data gaps
4. Most importantly identify an objective outcome target for our sector that could result in meaningful intervention in ensuring future packaging solutions that provide for a meaningful net environmental benefit

Key considerations outlined in this paper include, but are not limited to:

- Definitional considerations, including technical considerations for measuring/determining/verifying recycled content in products
- Possible product exemptions
- Source materials for post-consumer plastic resins (i.e., non-virgin plastics) [PCR]
- Technical challenges with availability/quality of PCRs

- Alternatives to PCRs (biopolymers and compostable polymers)

This Notice serves to confirm the intent to proceed with the development of new regulations in this regard. This is not a surprising step – and is certainly an approach we understood would be part of ECCCs vision to reduce plastics and plastic waste. CA Canada believes that this is an important first step and provides for an opportunity for our industry to proactively engage with shaping the direction of the proposed policy that is being contemplated. As a next step, as outlined above, this will be a key, 'not to be missed' feature of our upcoming Environmental Symposium on March 23rd, where we will be organizing some breakout sessions to start delving into detail with ECCC officials to further elaborate on the technical input that we will be highlighting in brief in the preliminary commentary that we will be preparing in response to this initial consultation (deadline: March 14, 2022).

Finally – REGISTER NOW for our Environmental Symposium

Administration of the New Substances program – Processing of Submissions document

The New Substances (NS) program is seeking comments on the attached "Administration of the New Substances program – Processing of Submissions" document. When finalized, it is set to replace the current New Substances Program Operational Approaches Manual, which was last updated in 2011. The document applies to both *New Substances Notification Regulations (Chemicals and Polymers)* and *New Substances Notification Regulations (Organisms)* submissions.

The purpose of the document is to provide a general overview of the submission process and its outcomes and to clarify the roles and responsibilities of both the NS program and its notifiers. It is expected to be particularly useful for new stakeholders who are unfamiliar with the NS program and the submission process.

The document acts as a complement to existing published guidance documents. As such, step-by-step instructions and detailed technical guidance continue to be provided separately in the draft Guidance Document for the Notification and Testing of New Chemicals and Polymers and the Guidelines for the Notification and Testing of New Substances: Living Organisms.

The publication of the document will allow the implementation and communication of operational changes to be effected faster. The NS program is committed to reviewing and updating the document as needed on an annual basis in order to reflect continuous operational changes and improvements.

There are several concurrent improvement initiatives that are associated with the development of the document. For example, the NS program intends to publish on its website a Confidential Search Request and a Pre-notification Consultation form. In addition, the NS program is looking at changing its Single Window online process to allow all submission types, including NSN organisms, to be submitted.

The NS program is seeking your feedback on the publication of this document. Comments provided by **March 11, 2022** will be taken into consideration during the development of the final document. Comments can be submitted by email to substances@ec.gc.ca.

Update on the Revised In Commerce List (R-ICL)

This is to advise you that the Final Notice on Removal of Substances with no Commercial Activity from the Revised In Commerce List was published in the *Canada Gazette* (Part I) on February 19, 2022. In addition, several website pages related to the R-ICL have been updated to provide information concerning the on-going administration of the R-ICL.

The *Canada Gazette* Notice lists 602 substances that were removed from the R-ICL as they were determined to have no stakeholders reporting commercial activity in Canada for use in products regulated under the *Food and Drugs Act*. Commercial activity was determined based on responses to a mandatory survey of commercial status conducted under the authority of S.71 of CEPA in 2017,as well as responses to the Notice of intent to remove low volume or discontinued substances from the Revised In Commerce List published in September 2020. A consultation document was also published in September 2020 and a voluntary follow-up survey was conducted in February 2021 to address uncertainties with some of the 2017 S.71 survey responses.

Substances removed from the R-ICL can still enter into Canadian commerce subject to applicable statutes, including the *New Substances Notification Regulations (Chemicals and Polymers)* made under the *Canadian Environmental Protection Act, 1999*.

As noted, several R-ICL related webpages have been updated, please see the list below.

Canada Gazette Notice (Part I) - Removal of Substances with no Commercial Activity from the Revised In Commerce List

Removal of substances with no commercial activity from the Revised In Commerce List

Webpage - About the Revised In Commerce List

https://www.canada.ca/en/health-canada/services/environmental-workplace-health/environmental-contaminants/drugs-personal-care-products/environmental-impact-initiative/commerce-list-food-drugs-act-substances/revised-commerce-list-food-drugs-act-substances-health-canada-1.html

Webpage - Approach for the prioritization of substances on the Revised In Commerce List

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/approach-prioritization-substances-revised-commerce-list.html

Webpage - Results of prioritization, status and outcome for substances on the Revised In Commerce List

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/results-prioritization-substances-revised-commerce-list.html

Webpage - Removal of substances from the Revised In Commerce List

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/removal-substances-revised-commerce-list.html

Webpage - The Revised In Commerce List is Closed to Nomination

https://www.canada.ca/en/health-canada/services/environmental-workplace-health/environmental-contaminants/drugs-personal-care-products/environmental-impact-initiative/commerce-list-food-drugs-act-substances/nomination-substances-revised-commerce-list.html

Webpage - Facts about the Revised In Commerce List

https://www.canada.ca/en/health-canada/services/environmental-workplace-health/environmental-contaminants/drugs-personal-care-products/environmental-impact-initiative/commerce-list-food-drugs-act-substances/frequently-asked-questions-faqs-commerce-list-food-drugs-act-substances.html

Webpage - Revised In Commerce List tracking table (previously known as Table of prioritization results of substances on the Revised In Commerce List)

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/results-prioritization-substances-revised-commerce-list/table-prioritization-results.html

Webpage - Revised In Commerce List

https://www.canada.ca/en/health-canada/services/environmental-workplace-health/environmental-contaminants/drugs-personal-care-products/environmental-impact-initiative/commerce-list-food-drugs-act-substances/revised-commerce-list-food-drugs-act-substances.html

Cosmetics Alliance Updates

Cosmétiques 101 - Introduction aux cosmétiques au Canada - Session De Formation Interactive

Vendredi le 25 mars 2022

2:00 pm - 4:30 pm

14h00 à 16h30

Session de formation en français

Conçue pour:

- Nouveaux employés
- Nouveaux members de Cosmetics Alliance
- Rappel

Objectifs

- Connaître le vocabulaire de cosmétiques au Canada.
- Comprendre la structure des lois canadiennes.
- Survol de la réglementation des cosmétiques.
- Faciliter l’accèss au marché Canadienne

*Veuillez noter que ceci est disponible uniquement aux membres de l'alliance de l'industrie cosmétiques qui ont un bureau officiellement déclaré dans la province de Québec.

La formation inclue des exercices, un questionnaire et un attestation de participation.

Seules les personnes inscrites en ligne seront en mesure de répondre au questionnaire et de recevoir l’attestation.

Fees/Honoraires

	Member/Membre	Non-member/ Non-membre
1-4 Delegates/délégués	$250 each/chaque	$395 each/chaque
5-10 Delegates/délégués	$225 each/chaque	$370 each/chaque
Over/sur 10 Delegates/délégués	$200 each/chaque	$345 each/chaque

Register/Registre

Save the Date - Virtual Spring Regulatory Workshop

Cosmetics Alliance Virtual Spring Regulatory Workshop is scheduled for Tuesday, May 17, 2022. Stay tuned for more information in the coming weeks.