Regulatory Essentials – April 28, 2021

Cosmetics Alliance Updates

Virtual Spring Regulatory Workshop – Register Today!

Get ready for our first ever Virtual Regulatory Workshop on June 1st – 2nd, 2021. Cosmetic Alliance Regulatory Workshop provides members with the opportunity to stay up-to-date and informed on "everything regulatory". Hear from government officials and Cosmetics Alliance staff on issues that will directly affect your business. Take part in our Member Engagement Session the next day to discuss what was heard the day before with your industry colleagues and CA Staff.

The regulatory workshop will also feature a new panel session with Health Canada's Director Generals:

Linsey Hollet – HPCD (ROEB)

Roger Charland - CHPSD

Natalie Page - NNHPD

along with CAC's President Darren Praznik.

This panel session will explore the future for the personal care product industry and how experiences over the last year can be leveraged in shaping the Self-Care Framework.

Do not miss out on this opportunity to engage with them and ask questions which matter to you.

Price of the workshop is per login, attendees can not share logins.

Workshop Preliminary Agenda

Member Engagement Session Agenda

Regulatory Workshop Details

Date: June 1, 2021

Time: 9:00 a.m. - 12:00 p.m. EDT

Location: Virtual

Cost: $350 (including Member Engagement Session)

Member Engagement Session

Date: June 2, 2021

Time: 9:00 a.m. - 10:30 a.m. EDT

Location: Virtual

Register

Inspiring the Future – Spotlight Feature (For All Members)

At our upcoming Virtual Regulatory Workshop, CA Canada is looking to build an opportunity to bring a spotlight on member company stories that demonstrate our industry's perseverance through the dark times of COVID. Help us uplift the collective spirits of our industry as we strive to adapt to the new world that was and will be moving forward.

We Need Your Help! On Tuesday, June 1st we will be looking to spotlight our member companies in a new and exciting way. We are looking for videos that highlight positive reflections about your company, your people, and/or your products and services as our industry looks to recover from the challenging times of COVID.

We will be spotlighting these videos and other visuals during our Virtual Regulatory Workshop and in our inspirational montage that will also be displayed on our website and social media channels. All participating companies will be entered in a draw to win one of three free registrations to our Virtual Regulatory Workshop. This includes companies that have already sent us materials (including images) over the last few months.

Send us your videos today!

Signup Now

2021 CA Annual General Meeting and Member Briefing

Please register for CA's Annual General Meeting and Virtual Member Briefing, featuring special guest *Natalie Page, new Director General of Health Canada's NNHPD* and the key Directorate leading Canada's Self-Care Framework. Also hear from, *Nielson's Francis Parisien* who will be speaking about the impacts of COVID-19 on the personal care products industry and will also explore upcoming trends. Both events are free and open to all members.

These presentations will be followed by CA's Annual General Meeting, which requires your company's representation.

Timeline of the day's events:

- Member Briefing 12:00 p.m. - 1:00 p.m.
- Annual General Meeting 1:00 p.m. - 1:15 p.m.

Don't forget to bring your lunch!

Register:

https://www.events.cosmeticsalliance.ca/product/agm2021/

2021 Annual General Meeting

Pursuant to CA's By-laws and requirements under the *Canada Not-for-Profit Corporations Act*, CA's Annual General Meeting will be held virtually on Thursday, May 6, 2021 at 1:00 p.m. - 1:15 p.m.

ITEMS OF BUSINESS:

In accordance with the By-Laws, the following items of business will be considered .

- Draft Minutes of the last Annual General Meeting held May 7, 2020 (click here)
- Auditor's Report and Audited Financial Statements for the year ending December 31, 2020 (click here)
- Appointment of Auditor for 2021 (click here)
- Omnibus Motion (click here)
- Nominations for CA 2021-2022 Board of Directors (click here)
- Other Business (click here)

The AGM will be followed at 1:20-3:00 by a Board of Directors Meeting (CA Board Members only). Microsoft Teams connection link is in Board Members' Outlook Calendar invitation.

VOTING

Please note that only Brand member companies are entitled to vote. Authorized representatives of Brand member companies have been provided with all materials which are subject to membership vote as well as a proxy form.

Should you have any questions, please do not hesitate to contact us.

Health Updates

Auditor General's 2021 Report – Natural Health Products Program Released

The Auditor General's 2021 Spring Report on Health Canada's Natural Health Products Program was tabled in the House of Commons on April 22, 2021 and has now been released to

The audit focused on whether Health Canada ensured that natural health products available for sale in Canada were safe and accurately represented to consumers.

An overview of the report is available here as well as the results of their national survey. We are analyzing internally and will provide a broader commentary in the coming days.

At first glance the report appears well-balanced and based on the presentation from NNHPD, we understand that a number of corrective actions have already been (or will shortly be) initiated by Health Canada. Briefly, of significant interest were the observations and recommendations regarding:

- The notable differences between how drugs and NHPs are presently regulated,
- Risk-based approach and oversight ; both of which speak to the need a level playing field, which is foundational to the Self-Care Framework; including considerations regarding standardizing GMPs, recall and cost-recovery provisions
- Labeling oversight and the need to ensure that labels are easily readable; which is aligned with NHP improved labelling initiatives which are presently subject to Phase 1 of SCF modernization efforts

Cosmetics Alliance Attends Health Products Compliance Directorate Bilateral Meeting

On April 27, Cosmetics Alliance attended the Bi-lateral Meeting with HPCD. In attendance from HPCD was Linsey Hollett, Mary Morgan, Kim Godard, Elizabeth Rached and Johnathan Mahdi. In Attendance from Cosmetics Alliance were Darren Praznik, Beta Montemayor, Richard Parcels, Linitha Ganesh and Margaret Turnbull from Colgate-Palmolive as the Vice-Chair of the Facility Compliance & Manufacturing Committee. Cosmetics Alliance requested updates on the COVID, NHP Inspection Pilot, Proactive Risk Management Projects and Regulatory Flexibilities. Going forward Cosmetics Alliance will be having regular Bi-lateral meetings with HPCD. Below is the presentation deck for your reference.

HPCD Overview Presentation Deck

HPCD Updates Presentation Deck

Nitrosamine Update to Market Authorisation Holders of Human Pharmaceutical Products

All DIN holders should have received notice from Health Canada on December 16, 2020 with details of a compliance action plan for nitrosamine assessment in your DIN products.

This exercise was a direct result of a Cosmetics Alliance's ask at the last nitrosamines multi-stakeholder session from February 10, 2021, for a type of compliance action plan given some stakeholders can have delays due to the sheer volumes of DINs (can have up to 200 DINs).

This follow-up with MAHs is to confirm risk assessments have been completed. You are requested to indicate your current status with respect to completion of Step 1 -Risk Assessments

As part of Health Canada's efforts to mitigate the risk of presence of nitrosamine impurities in all APIs and drug products, Health Canada had requested in its letter of October 2, 2019, that MAHs follow a three-step process for assessing and controlling the risk of nitrosamines in their drug products containing chemically synthesized APIs. The deadline for completing the risk assessments (Step 1) was extended to March 31, 2021.

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MAH Letter – EN/FR

Details Regarding Incomplete Risk Assessments (Annex 3) – EN/FR

Nitrosamines Impurities – Summary of Completed Risk assessments – EN/FR

2020 Annual Surveillance Report from Health Canada's Consumer Product Safety Program

The Triage and Surveillance Division of the Consumer and Hazardous Product Safety Directorate (CHPSD) released the 2020 Annual Surveillance Report, which identifies, presents and summarizes all incidents reported to the CPSP. This report highlights the top 10 reported consumer products and cosmetics, with further analysis on hazards, injuries and fatalities. The report does highlight cosmetics but do note that reporting of cosmetics is voluntary.

Canada's approach to onsite inspections during COVID-19: Notice

During the COVID-19 pandemic, Health Canada continues to take a risk-based approach to inspections.

Onsite work remains a key tool in helping Health Canada fulfill their mandate to deliver essential inspection activities. Health Canada uses remote or virtual tools to complement onsite inspection activities.

When onsite activities are conducted, Health Canada is implementing appropriate COVID-19 mitigation measures in adherence with public health guidance. Along with COVID-19 screening self-assessments, such measures include:

- practising social distancing
- practising good respiratory etiquette and hand hygiene
- equipping inspectors with sanitation supplies, non-medical masks, and other required PPE
- making adjustments for additional provincial, territorial, local and community specific public health guidance, where applicable

Health Canada inspectors are governed by applicable acts and regulations and follow procedures referenced in A Guide to Health Canada Inspections. As such, inspectors continue to have the power to enter any place or premises at any reasonable time where:

- a regulated activity is being conducted or
- a regulated product, article, device or thing, or relevant document is located

Anyone at the place of the inspection is legally required to give the inspector all reasonable assistance.

To stay safe and help limit the spread of COVID-19, Health Canada expects that public health guidance and mitigation measures will be followed while the inspector is onsite. Consideration for the health and safety of inspectors and regulated parties is a joint responsibility. Where it isn't possible to reduce the risks of COVID-19, other options may be explored.

Health Canada will continue to monitor developments regarding COVID-19 and adjust plans for onsite delivery, as needed.

CETA Enables GMP Certificates of Compliance for Regulatory Audits Outside of their Jurisdictions

Prior to April 1st, 2021, a GMP Certificate of Compliance (CoC) issued by Health Canada or an MRA country for an inspection conducted outside of their respective jurisdictions was considered insufficient evidence to support a foreign site listed or to-be listed on a Drug

Establishment Licence. Stakeholders were required to submit a copy of the CoC along with the full inspection report.

Effective April 1st, 2021 Canada and the European Union (EU) officially recognized Good Manufacturing Practices (GMP) inspections conducted outside of their respective jurisdictions (i.e. extra-jurisdictional inspections) under the Comprehensive Economic and Trade Agreement (CETA) – *Protocol on the Mutual Recognition of the Compliance and Enforcement Programme regarding Good Manufacturing Practices for Pharmaceutical Products* for drugs in **finished dosage form** (active pharmaceutical ingredients are not included). This new measure is intended to reduce regulatory burden for Canadian importers.

As a reminder, the United Kingdom is no longer part of the UK-MRA and that the United Kingdom and Canada have entered into the Canada-UK Trade Continuity Agreement whereby Canada and the UK will continue to recognize Certificates of GMP Compliance issued by each country's regulatory agencies; and will continue to accept batch testing certificates issued by a manufacturer without re-control of that batch at import.

As a reminder, the products in the respective regions are required to be regulated as drugs in each jurisdiction.

Inspections conducted on or after April 1, 2021 are eligible for extra-jurisdictional CoCs. You may add or maintain a foreign building on your DEL by submitting a request to Health Canada to obtain the extra-jurisdictional CoC from the equivalent EU Regulatory Authority. In this case, you do not need to submit the full GMP evidence to Health Canada for review. To initiate the request, please specify in a cover letter and FRM-0033 (*Drug Establishment Licence Application Form*) that an extra-jurisdictional CoC is available for the foreign building. For further instructions, please email: Hc.DEL.Questions-LEPPP.SC@canada.ca.

Forward Regulatory Plan – Amendments to the Cosmetics Regulations

Health Canada is proposing to introduce a requirement under the Cosmetic Regulations for the disclosure of specific fragrance allergens on the product label. In addition, Health Canada is proposing to amend the regulations to enhance regulatory oversight for cosmetics.

The amended regulations would inform consumers about the presence of specific fragrance allergens, outside of the term "parfum" that are present in the product. This would allow consumers to avoid products containing fragrance allergens to which they may be sensitive.

Cosmetics Alliance is in the process of reviewing this proposed amendment and will be engaging with its PCMA committee on next steps. A boarder detailed communication will be sent out to members once our analysis is complete.

US FDA Public Workshop: The Non-prescription Drug Facts Label in a Changing Consumer Marketplace 2021"

FDA is announcing a public virtual workshop online on June 9, 2021 from 8:30 a.m. to 4:30 p.m. EST.

The purpose of the public workshop is to evaluate the data and information currently available on consumer comprehension of the non-prescription Drug Facts Label (DFL) and discuss areas where improvements could be made to the format and content of the DFL. The DFL is intended to enable consumers to appropriately self-select and use non-prescription drug products safely and effectively. FDA is seeking ways to optimize the DFL for consumer use so that it is robust, user-friendly, adaptable for use with new technologies, and compatible with traditional text/paper-based presentation. More information about the virtual public workshop is available on FDA's workshop webpage.

Those interested in attending the virtual workshop are encouraged to register early via the Eventbrite registration page.

In addition to providing input at the public meeting, stakeholders are invited to provide their perspectives on the discussion topics and submit research, data, or information relevant to the public workshop topics to the public docket. The docket closes on August 10, 2021.

Environmental Updates

Various Publications Under the Chemicals Management Plan

1. Final Screening Assessment Report for Talc

The Final Screening Assessment Report (FSAR) on talc under the Canadian Environmental Protection Act, 1999 (CEPA) was published today and begins a 60-day comment period.

The conclusions outlined in the FSAR uphold the original findings of the draft assessment published in 2018, namely that talc is concluded to be 'CEPA-Toxic' on the basis of:

- concerns with the possible association of perineal talc use with increased incidence of ovarian cancer; and
- potential inhalation risks associated with the use of talc in certain topical products (in loose powder forms).

Cosmetics Alliance disagrees with the final assessment as it is not supported by the 40+ years of scientific evidence and ignores important new safety data shared with Health Canada during the assessment process. The conclusion that perineal talc use may lead to an increased risk of

ovarian cancer is not supported and the inhalation risk association with the use of talc in topical products ignores the more than 4 decades of in-market safety evidence.

While we are still reviewing the FSAR in detail, we do not believe that this assessment captures the full weight or strength of the scientific evidence. We will be engaging with officials to express our concerns. We will also be considering next steps in the CEPA process which could include a request for the appointment of an independent Board of Review depending on the proposed risk mitigation measures.

Cosmetics Alliance has posted a Statement on our public facing website. If your company receives any inquiries, please use this statement accordingly or feel free to direct them to Susan Nieuwhof (snieuwhof@cosmeticsalliance.ca, 647-980-5161).

2. Informed substitution within Canada's chemicals program

A summary of feedback from the consultation -Informed substitution within Canada's chemicals program was published. Health Canada and Environment and Climate Change Canada launched an online consultation on January 16, 2019, which closed on March 18, 2019, to seek input from Canadians in response to a study that was posted entitled "Options for advancing informed substitution and alternatives assessment within Canada's chemicals program".

Feedback received through this consultation process will help define the scope for subsequent consultations on how the Government of Canada could modernize chemicals management in Canada and to inform the potential role of Government in informed substitution and alternative assessments.

3. Notice of Intent for Per- and polyfluoroalkyl substances (PFAS)

On April 23, the Chemicals Management Plan released the Notice of intent to address the broad class of per- and polyfluoroalkyl substances (PFAS). Please note that is an unusual step under the CMP (Notice of Activities) specifically providing for consultation on a grouping**.** Although there have been other grouping initiatives before, most of the grouping initiatives have been Government asking for concurrence as to their grouping approach; this one seems to be looking for feedback or suggestions on whether a grouping should be pursued, and perhaps looking for some recommendations on how to group or how to approach such grouping. The 'planned activities' that would be subject to the grouping appear to span risk assessment, management and information gathering considerations.

Please take the time to review the Notice of Intent and provide us with any input, suggestion or consideration you may have to regulatory@cosmeticsalliance.ca. CA will review the Notice of Intent and will collaborate with CEPA ICG and other trade associations to determine how to proceed.

Key Ingredient Developments from Europe – Recent SCCS Opinions

The SCCS final opinions of Resorcinol, Propylparaben, Benzophenone-3, Octocrylene was recently published. The Opinions of all 4 ingredients were positive as it was supportive of safe use in all cases with some risks associated with certain use concentrations and formats (as observed in benzophenone 3 and octocrylene). Revised maximum concentrations of use are outlined to substantiate continued safe use of these ingredients. The Opinion for Propylparabens are in line with the representations CA submitted in December for the Draft Screening Assessment for the Parabens Grouping which is significant as it provides for an opportunity to reinforce with Canadian officials that these recent SCCS findings mirror the recommendations CA made pertaining to Propylparaben. Conclusions regarding potential endocrine modulation considerations are relatively reasonable and balanced although it does not yet make any corresponding conclusions in either direction.

Please take the time to review the final opinions below and let us know if you have any questions or concerns.

1. z Resorcinol
   https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_241.pdf

2. Propylparaben
   https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_243.pdf

3. Benzophenone-3
   https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_247.pdf

4. Octocrylene
   https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_249.pdf

Extension - Voluntary Information Gathering on Industry Supply Chain Information Sharing in Canada

Further to CA's Notice on April 13, 2021, the survey deadline has now been extended to May 17, 2021. Given this survey is **voluntary**, CA Canada will be engaging generically on this file on behalf of our membership to ensure that officials appreciate that these transparency considerations should not extend to cosmetic/personal care products, given the provisions already in place. Of course, should members wish to engage with the survey, that remains a possibility; however, we would suggest that responding to the survey is likely to require significantly more effort to complete than the 30 – 40 minutes as indicated in the survey. Instead, should members choose to engage, we would recommend highlighting the important reality that for cosmetic/personal care products – there is already sufficient transparency built into mandatory labelling provisions that ensure that consumers, retailers and all stakeholders have sufficient information to understand what substances are comprised within finished cosmetic/personal care goods. Any information beyond these requirements would stray into proprietary details (i.e. use concentration information) that would not be relevant in addressing the base concerns that underpin the survey. It may also be worthwhile to point out that cosmetic/personal care uses of substances are well featured in CMP assessments already – which in of itself demonstrates that relevant and meaningful supply chain information is already readily available across the supply chain – at least from a cosmetic/personal care perspective.

CMP Publications Plan for April to June 2021

Canada's Chemicals Management Plan (CMP) releases yesterday the Publication Plan for April to June 2021 listed below. The program anticipates sharing the Publications Plan for July to September 2021 by summer 2021.

The publications of importance to our industry are highlighted in yellow below. Please let us know if you have any questions or concerns.

Publications targeted for April to June
Acetonitrile FSAR[b]
Additional Risk Characterization Document for zinc and its compounds[c]
Aluminium, Selenium and Siloxanes Draft FEQGs[d]

Anthraquinones Group FSAR[b]
Coal Tars and their Distillates FSAR[b]
Copper FEQGs[d]
Diethylenetriaminepenta(methylene-phosphonic acid) FSAR[b]
Monocyclic and Bicyclic Sesquiterpenes Group DSAR[a]
Phenol, 4-chloro-3-methyl- FSAR[b]
Talc 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] The DSAR for zinc and its compounds was originally published on June 29, 2019. Additional ecological exposure information has since become available; therefore, an additional risk characterization document will be published.

[d] Federal Environmental Quality Guidelines (FEQGs) are recommendations in quantitative or qualitative terms to support federal environmental quality monitoring activities.

Note: Group names are not final and may change