Regulatory Essentials – November 10, 2021

Cosmetics Alliance Fall Virtual Regulatory Workshop – Register Now!

Regulatory Workshop Details:

Date: December 9, 2021
Time: 8:30 am – 12:30 pm EST
Location: Virtual
Cost: $350 (including Member Engagement Session)
$50 off for all additional attendees from the same member company

Member Engagement Session:

Date: December 10, 2021
Time: 9:00 am – 11:00 am EST
Location: Virtual

Get ready for our Fall Virtual Regulatory Workshop on December 9-10, 2021. Cosmetic Alliance Regulatory Workshops provide 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. You also do not want to miss the Member Engagement Session the next day to discuss what was heard the day before with your industry colleagues and CA Staff.
Price of the workshop is per login; attendees can not share logins.

Cancellation Deadline

Registration fees will be refunded in full for cancellations received before November 26, 2021. Cancellations received after November 26, 2021, will not be refunded. Substitutions permitted at any time from the same company.

Register

Health Updates

Current Status of Technical Grade Ethanol (TGE) in Hand Sanitizers

Due to the COVID-19 pandemic, Health Canada implemented interim measures, authorizing certain products to be sold in Canada. These products may not fully meet regulatory requirements, but do not compromise the safety of Canadians. Health Canada authorized the importation of products that are authorized or registered in other jurisdictions where the regulatory frameworks and quality assurances are similar. Please note that not all disinfectant products are eligible for temporary importation under the interim measure. Various criteria are used to deem a product eligible for temporary importation under the interim measure, one of them being "the product does not contain technical grade ethanol".

Health Canada has granted temporary authorization to specific suppliers to produce technical-grade ethanol (TGE) for the production of hand sanitizer until December 31, 2021. Please note that authorized suppliers of TGE are not distributors of TGE or manufacturers of hand sanitizer containing TGE.

Importation of hand sanitizers containing TGE has not been extended as there were no requests for extension received from authorized manufacturers/importers. As such, any importation of hand sanitizer containing TGE should have ceased June 30, 2021.

FAQ: Under the listing of Manufacturers of hand sanitizers and hard-surface disinfectants using TGA, there are products listed with "Authorized to sell until" …some of the dates listed are beyond Dec 31, 2021. What does this mean?

Prior to manufacturing hand sanitizer containing TGE, manufacturers must first submit a technical-grade ethanol notification form and wait until the issuance of a no objection letter (NOL) from Health Canada. Therefore, companies may not manufacture hand sanitizer containing TGE unless they have received a NOL and are sourcing ethanol from an authorized TGE supplier. Please refer to the Manufacturers of hand sanitizers and hard-surface disinfectants using technical-grade ethanol webpage for a complete list of companies who have been granted a NOL. Please note that the "Authorized to sell until" column indicates which companies have been provided an extension until March 31, 2022, to distribute their hand sanitizer containing TGE and which companies ceased distribution of hand sanitizers containing TGE by the June 30, 2021 date.

As stated above, authorized suppliers of TGE are not distributors of TGE or manufacturers of hand sanitizer containing TGE. Suppliers are authorized to produce TGE until December 31, 2021. Distributors who obtained the latest extension are authorized to resell TGE obtained from an approved supplier until February 15, 2022. Manufacturers who have obtained an updated NOL are authorized to sell hand sanitizers containing TGE until March 31, 2022. After March 31, 2022, no hand sanitizers containing TGE are permitted to be released onto the Canadian market.

Cosmetics Alliance encourages you to reach out to the NNHPD if you were not contacted as part of their outreach for extensions.

Summary Performance Standards Call with Natural & Non-prescription Health Products Directorate

The NNHPD held their latest Performance Standard call on October 28th. The update included the following themes:

- NHP Workload Update
    - Product application
    - Site licence applications
- COVID Site Licence transition update

- System update
- Informatics, analytics, and product trends

NHP Workload Update

- Product applications
    - Non-COVID Submission Summary (April 2021 to Sep 2021)
        - Licensed 5,045 NHPs
        - 52% Class I
            - Continue to meet 90% performance against the 60-day standard for new applications and amendments
                - Refusal rate: 14%
        - 15% Class II
            - Continue to meet 90% performance against the 90-day standard for new applications and amendments
                - Refusal rate: 36%
        - 33% Class III
            - 57% performance year-to-date for new applications and amendments against the 210-day standard
                - Refusal rate: 19%
        - Of this, 30% of applicants have received correspondence since the issuance of acknowledgements of receipt. A small percentage of this 30% have not received any further correspondence. CAC has asked if the NNHPD would at least let applicants know that their submissions are progressing. NNHPD indicated they would consider a communication to stakeholders in this situation.
        - Notifications
            - Completed 99% of notifications received prior to 2021.
            - 46% of notifications received in 2021 have been completed
        - Total refusals: 1,390 submissions

- Site licence applications
    - Non-COVID Submission Summary (April 2021 to Sep 2021)
        - Licensed or renewed 362 sites
        - Refused 213 submissions
        - Stream I: 54% year-to-date performance for new and amendments
            - Refusal rate: 31%
        - Stream II: 86.6% year-t0-date performance for new and amendments
            - Refusal rate: 36%
        - Renewals
            - Completed 162 this fiscal
            - Refusals: 35.5%
            - Reminder that the acknowledgement letter includes an extension of the period of validity until a decision is issued on the renewal
            - NNHPD continues to apply a risk-based approach to renewals, as implemented for the December 1st renewals.
- Client Services

- Received 8,887 inquiries
- 97% of inquiries received a response

COVID Site Licence Transition Update

- Reminder: applicants were required to demonstrate compliance with the GMPs (part 3 of the NHPR), including testing.
- Clear refusal criteria, with no IRNs issued for incomplete applications.
- SL applicants who applied by September 30, 2021 can continue activities under their interim COVID-SL until a licensing decision is issued.
- 174 companies submitted a transition application
- 107 COVID-19 Site Licence holders provided an administratively complete application on-time
  - Refusal rate for incomplete applications: 35%
- Companies who did not apply have been asked to confirm by October 25th that they have ceased activities.

SYSTEMS UPDATE

- Web PLA form version 4.3 – to be released Winter 2022
  - Features: validation all monographs
  - Improved support for kit submissions
  - Improved NMI filtering
  - Improved error messages
- Decommissioning web form 3.0 Winter 2022
  - Version 3.0 of the web form will no longer be able to finalize
  - Still able to view files and reply to IRNs
- Electronic site form – Winter 2022
  - Improvements to assist in the processing and screening stages with more success and a reduction in the need for IRNs
  - Improved in-form validation
  - Introduction of a notification table
- Secure Portal
  - Questionnaire will be sent out to licence holders and associations in the coming weeks to seek feedback on features of existing HC secure portals and which features would be considered essential

INFORMATICS, ANALYTICS, AND PRODUCT TRENDS

- Improved monitoring and tracking from the moment a file enters ePost until a decision is rendered
- Electronic forms and implementation of automation to allow reduction in error rates from ePost downloads, increased tracking and monitoring of submissions, delivering on a more accurate workload
- Areas of focus: automated tools, enhanced workload tracking and monitoring, trend and forecasting identification, advanced analytics for process optimization and efficiencies

Please note the presentation deck will be shared once CA receives it from the NNHPD.

US FDA Support for Cosmetic Allergen Labeling Has Foundation in Consumers' 'Right to Know'

Health Canada is not the only governing authority looking into Cosmetic Allergen labelling as outlined by Europe (26 established contact allergens must be identified on product packaging). The Food & Drug Administration (FDA) agrees with the EU on identifying allergens and has been researching allergens, examining definitions, occurrences and the best approaches for public outreach, in addition to discussing its public health concerns with industry trade associations. The FDA looking at the 26 EU allergens is important for a level playing field and it lends credence to Cosmetics Alliance's commentary on the Cosmetic Regulatory Reforms which was submitted to the Consumer & Hazardous Products Directorate on October 27, 2021.

Notice – Evaluation of the Consumer Product Safety Program: Key Informant Interviews

Cosmetics Alliance would like to inform you that the Office of Audit and Evaluation (OAE) of Health Canada/Public Health Agency of Canada is currently undertaking an Evaluation of the Consumer Product Safety Program. This evaluation is being conducted to gather information about the design, delivery and/or effectiveness of program activities in order to inform and support senior management in their decision making, improvements, innovation and accountability for the program. The evaluation will examine the impact and efficiency of Health Canada's consumer product safety activities, as well as the influence of strategic partnerships on the achievement of program objectives. This project covers activities for the period of 2017-18 to 2021-22.

The evaluation will include information from multiple lines of evidence, including interviews with individual companies, associations and stakeholders in the cosmetics and personal care products industry.

Passing of Warren Pratt at Natural & Non-prescription Health Products Directorate

It is with great sadness that we share with you the news that our colleague Warren Pratt of the NNHPD's Submission Management Division passed away suddenly on July 24th.

Many of you who work directly with the NNHPD will recall Warren since the early days of the Natural Health Products Regulations implementation back in 2004.

For further details please see Obituary

Environmental Updates

Summary of Recently Released CMP Publications

Recently, Environment & Climate Change Canada (ECCC) released the publications listed below on November 5, 2021:

- Approach for a Subset of Organic and Inorganic Substances Prioritized Under the Chemicals Management Plan
- Draft Screening Assessment and Risk Management Scope for Flame Retardants Group
- Draft Screening Assessment and Risk Management Scope for Methylstyrenated phenol

Although none of the publications are likely to be directly relevant from a cosmetic / personal care products perspective, all three publications offer a number of interesting precedents and/or considerations that may be helpful in support of future risk assessment and/or risk management activities under the CMP. We have highlighted some of these key observations, below.

Approach for a Subset of Organic and Inorganic Substances Prioritized Under the Chemicals Management Plan:

This approach addresses 9 organic and inorganic substances that were identified as priorities for assessment as they met the categorization criteria CEPA or were considered a priority based on other human health concerns. It is proposed that these substances do not need further assessment.

Science Approach Document (SCIAD)

The approach outlined for Vitamin D3 is intriguing as it shows a very simplistic and rather pragmatic approach to a substance that provide for specific health benefits (where no corresponding ecological risks are identified). This is the first time under the CMP where we have seen such an approach taken. As you are aware, CA Canada has long and repeatedly advocated for the 'best-placed Act' approach to guide CMP related decisions. In particular, there are many circumstances in the past where we have implored officials to consider pre- and post-market considerations in relation to substances in products regulated under the Food and Drug Act (F&DA). Perhaps this suggests a willing change in approach that we could potential leverage moving forward.

This may provide for a corresponding precedent upon which to contextualize future potential assessments of greater relevance from a cosmetic/personal care perspective. In this regard, CA Canada will be undertaking a more in depth review of this SCIAD to get a broader sense as to the underlying policy precedent that may potentially be supported for other assessments, moving forward.

Flame Retardants Group:
The draft screening assessment for the Flame Retardants group has been published. It is proposed to conclude that IPPP may be harmful to the environment and to human health and meets the criteria under CEPA. It is also proposed to conclude that TPHP, BPDP, BDMEPPP and IDDP may be harmful to the environment and meet the criteria under of CEPA, while TEP may be harmful to human health. A risk management scope has been published concurrently to initiate discussions with stakeholders on the risk management options being considered.

Draft Screening Assessment
Risk Management Scope
Canada Gazette Notice

Overall, this Grouping carries a high profile, given how flame retardants writ large have been the subject of significant public scrutiny. Given the relative breadth of the proposed assessment and findings (both environmental and human health risks) this DSAR represents provides for some important insights. It also shows once again that a grouping approach can be delineating and that a grouped assessment does not necessarily need to reflect a generic conclusion applicable to all substances in a group. This is critical, as we know that grouping strategies are an important means under the CMP upon which to prioritize and to pursue risk assessment/management activities for substances within a specific class or with specific functionalities.

Methylstyrenated phenol:

The draft screening assessment for methylstyrenated phenol has been published. It is proposed to conclude that the substance may be harmful to the environment and meets the criteria under CEPA. A risk management scope has been published concurrently to initiate discussions with stakeholders on the risk management options being considered.

Draft Screening Assessment
Risk Management Scope
Canada Gazette Notice

Finally, this DSAR provides for an illustrative snapshoot as to ECCC's approach to a substance that is proposed to meet the criteria for virtual elimination (VE), based on PBT considerations.

Again, although the substances covered by these publications are unlikely to be of direct interest from a cosmetic / personal care perspective, we welcome any input/thoughts on the context and observations highlighted above.

Post-Consumer Waste Update

Recently Published Waste Updates

Blue Box Rule Creator PROs Now Confirmed

Three Blue Box PROs have qualified as rule creators, as confirmed by the Authority on November 1, 2021. Rule creators are responsible for developing the rules that will outline how producers are assigned collection services in the allocation table. Learn more here.

Authority agrees to Stewardship Ontario assignment of its primary service provider

The Authority has agreed with Stewardship Ontario's proposal to assign, with conditions, its master service agreement with its primary service provider Canadian Stewardship Services Alliance (CSSA) to Resource Recovery Alliance, a producer responsibility organization under the new Blue Box Regulation established by GFL Environmental Inc. as part of its proposed acquisition of CSSA. Learn more here.

Cosmetics Alliance Update

Cosmetics 101 - Introduction to Cosmetics in Canada

NOW OFFERING TWO DATES TO CHOOSE FROM

Dates: November 16, 2021, or November 23, 2021

Time: 1:00 pm - 3:00 pm EST

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

This popular program is designed for individuals who are: New to the Industry

- New Employees
- New Cosmetics Alliance Members
- or as a Refresher Course

Objectives:

- Learn the language of cosmetics in Canada

- Understand the set-up of Canadian Law
- Overview of the Cosmetic Regulations
- Enable attendees to access the Canadian market

Training will include exercises, a quiz, and a training certificate for your training file.

Only those electronically registered will be able to take the quiz and receive a training certificate

Register – November 16, 2021; November 23, 2021