Regulatory Essentials – September 19, 2018

Cosmetics Alliance Updates

Register for Cosmetics Alliance Fall Regulatory Workshop

While Summer might almost be over, Fall is definitely something to look forward to as Cosmetics Alliance will be hosting its annual Fall Regulatory Workshop. This year's Fall Regulatory Workshop will be on:

Date: Wednesday, October 10, 2018
Registration: 8:00 a.m. - 8:30 a.m.
Workshop: 8:30 a.m. - 4:30 p.m.
Location: The Omni King Edward Hotel, Toronto

View Preliminary Agenda

Cosmetics Alliance Regulatory Workshops provide members with the opportunity to stay up-to-date and informed on "everything regulatory". You won't want to miss this opportunity to hear from government officials, industry experts and Cosmetics Alliance staff first hand on issues that will directly affect your business.

Member Engagement Session:

Cosmetics Alliance will be hosting a Member Engagement Session at the end of the Workshop, so be sure to attend the whole day. This session will provide an opportunity for members to share their concerns and issues with Cosmetics Alliance staff and fellow attendees. Workshop delegates are encouraged to plan their travel arrangements accordingly to ensure active participation for this one-of-a-kind setting.

Health Updates

Health Canada's Marketed Health Products Directorate (MHPD) to Publish Summary Safety Review on Sunscreen Products

Members who manufacture/formulate and/or import sunscreen products will be receiving (if not already) an Advanced Notice from Health Canada's Marketed Health Products Directorate (MHPD) indicating their intent to publish their '***Summary Safety Review'*** (SSR) regarding potential skin reactions possibly attributable to sunscreen products. This publication represents the outcomes and recommendations from Health Canada's review and analysis of what Health Canada has characterized as "… a greater than usual number of reports describing skin reactions with the use of some sunscreen products", in addition to increasing media scrutiny regarding these same observations. We understand that this report represents Health Canada's attempt to be open and transparent and to notify Canadians as to the outcomes of this assessment and proposed action undertaken as a result of this review.

CA believes that the ultimate intent of this publication is for Health Canada to accomplish the following:

- Inform consumers that they have undertaken a comprehensive review of these 'trending' observations and demonstrate action (to show that they have heard from Canadians)

- Thereby, proposing an enhancement of the current required label warnings to ensure that Canadians are “protected”

The report’s recommendation signals the potential need to update labels that will take significant time and effort; with little to no added benefit to consumer protection.

CA has outreached to senior officials at both MHPD and the Natural and Non-Prescription Drug Product Directorate (NNHPD), whom is presently working on an updated sunscreen monograph (in support of Phase 1 of the Self Care Framework) to express our concerns with the recommendations as presented. We have requested meetings to review these concerns and to clarify/confirm MHPD’s ultimate intent with these recommendations and to ensure that Health Canada understands by proceeding with this publication as drafted, this will result in significant questions and pressures being brought to bear on both MHPD and NNHPD. It is critical that changes that impact on-market product and that compel label changes need to provide a net benefit to consumers. We have signal support for the overall intent as understood but will be strongly objecting to the recommendation as proposed, as it does nothing to address the underlying intent as outlined.

Furthermore, we will be following up with NNHPD to discuss the implications that these recommendations may ultimately have with the work they are pursuing regarding Phase 1 of the SCF, specifically the updating of the sunscreen monograph. We would not want to see the inclusion of revised directions for use and warning statements that are overly specific, and therefore inherently less protective of consumers that the generic warning already required under the present monograph.

NEXT STEPS

- CA Canada will look to secure the above-referenced meeting with MHPD and NNHPD officials, and escalate to senior management as necessary
- Encourage NNHPD and MHPD to delay publication as drafted (or at least to amend or remove the recommendation as outlined) and address these developments with our members at our upcoming Regulatory Workshop in early October
- Ensure that any corresponding revisions to the sunscreen monograph (soon to be published by NNHPD for consultation) reflect these key observations

Please do not hesitate to contact your CA Regulatory Team (regulatory@ccosmeticsalliance.ca) if you have any questions or wish to discuss these emerging developments in further detail.

Management of Product License Applications (MAP) 60 Day Written Feedback Period

The Natural and Non-prescription Health Products Directorate (NNHPD) is undertaking updates to its Natural Health Products Management of Applications Policy (NHP MAP) for Natural Health Products (NHPs). As such, the NNHPD is launching a feedback period of 60-days to which stakeholders have been invited to participate. NNHPD will also be holding two Q&A webinar sessions. The French session will take place on September 26 from 10:00 a.m. to 12:00 p.m. and the English session on September 27 from 1:00 p.m. to 3:00 p.m. If you would like to participate in either the French or English sessions please let NNHPD know which session you would like to register for by responding to HC.nnhpd.consultation-dpsnso.SC@canada.ca.

Please provide your name, title, and association. The registration for the webinar will be available until September 24, 2018.

Draft MAP for NHPs – EN

Draft MAP for NHPs - FR

Feedback Template

Please send your input regarding the draft MAP by November 5, 2018 to HC.nnhpd.consultation-dpsnso.SC@canada.ca .

California Law Passed on Ingredient Labelling for Professional Cosmetics

The *Sherman Food, Drug and Cosmetic Law* in California regulates the labelling of Cosmetics in that state. This law was amended to extend ingredient labelling to professional cosmetics manufactured on or after July 1, 2020.

The USFDA regulates cosmetic labelling under both the Federal Food Drug and Cosmetics Act (FDCA) and the Fair Packaging and Labelling Act (FPLA). As the FPLA applies to products sold only at the retail level, professional products are excluded from that Act. Ingredient labelling is not mandated by the FDCA but by the FPLA.

The complete amendment may be found at https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB2775

As you should be aware, cosmetic ingredient labelling for retail, sample and professional products are required to list ingredients for Canada.

Natural Health Product Good Manufacturing Practices Webinar Materials

On September 18, 2018, Health Canada hosted a Webinar to promote compliance with and provide guidance on Natural Health Products (NHPs) Good Manufacturing Practices (GMP). Below are the materials from the Webinar.

Good Manufacturing Practices Webinar – EN

Good Manufacturing Practices Webinar – FR

Natural Health Product Good Manufacturing Practices Webinar – EN

Natural Health Product Good Manufacturing Practices Webinar – FR

Regulatory Cooperation Council

The Assessment Collaboration Framework between the United States Environmental Protection Agency, Environment and Climate Change Canada and Health Canada was published. The Assessment Collaboration Framework: Canada-United States Rolling Work Plan was also published. The Assessment Collaboration Framework between the United States Environmental Protection Agency, Environment and Climate Change Canada, and Health Canada aims to facilitate and enhance collaboration between the U.S. EPA, ECCC, and HC for the risk-based assessment of chemicals within their respective legislative and regulatory contexts. Stakeholder engagement and broad communication to the public are additional goals

Notice to Impacted Stakeholders – Green Tea Extract (GTE)

On September 14, 2018, the Natural and Non-Prescription Health Products Directorate (NNHPD) issued reminder notices to license holders with products containing Green Tea Extract (GTE) as a medicinal ingredient to request changes to licences and labels. As a means of facilitating the requested revisions, the NNHPD has developed a GTE Amendment Attestation Form (attached) to be submitted for each product containing GTE as a MI. This attestation form must be signed by the Senior Official of the company holding the licence and returned to the NNHPD by November 14, 2018. Licence holders are encouraged to use the advanced search function of the Licensed Natural Health Products Database (LNHPD) to determine which of their active products contain GTE by searching for "Camellia sinensis" as a medicinal ingredient.

Please be advised that failure to provide a completed attestation form will result in regulatory action pursuant to sections 16 – 17 of the Natural Health Products Regulation (NHPR).

Please contact the Risk Management Division by email at HC.RMD.Communication-DGR.SC@canada.ca with any questions.

Green Tea Extract Hepatoxicity - EN

Green Tea Monograph - EN

Green Tea Extract Hepatoxicity – FR

Green Tea Monograph – FR

Notification for the Voluntary Public Engagement Initiative of the New Substances Program

This is to inform you that a new summary of notification has been published on the New Substances (NS) Program website. In an effort to engage Canadians in the risk assessment process of higher organisms regulated under the *New Substances Notification Regulation (Organisms)*, Environment and Climate Change Canada and Health Canada are working with notifiers on a voluntary basis to facilitate greater public engagement. The NS Program has published a summary of notification for AquAdvantage® salmon. Through this initiative, the public will be given the opportunity to provide scientific information and test data that could inform the risk assessment process. The new initiative can be found here.

Environmental Updates

Publication of the Draft Screening Assessment of Nitro Musks

Environment and Climate Change Canada (ECCC) and Health Canada (HC) published their Draft Screening Assessment (DSAR) for the Nitro Musks Grouping under the Canadian Chemicals Management Plan (CMP). This grouping includes the following two discrete substances:

CASRN	INCI NAME	COMMON NAME	CHEMICAL NAME

81-14-1	Musk Ketone	Musk ketone (MK)	Ethanone, 1-[4-(1,1-dimethylethyl)-2,6-dimethyl-3,5-dinitrophenyl]-
81-15-2		Musk xylene (MX)	Benzene, 1-(1,1-0dimethylethyl)-3,5-dimethyl-2,4,6-trinitro-

Both of these substances primarily enter the Canadian market as constituents of fragrance ingredients. Musk ketone is associated with fragrances in cosmetic and personal care products but is IFRA restricted (with required purity specifications). Musk xylene, is IFRA prohibited, and although historically used in some fragrance ingredients, is no longer in use. However, we understand that musk xylene may be present as an impurity (0.1%) in some fragrance preparations. It is proposed that musk ketone and musk xylene DO NOT meet any of the criteria for "CEPA-toxicity" as outlined under Section 64 of CEPA and no further risk management action is proposed at this time. There is a 60-Day Comment Period for submitting input regarding these DSAR findings. Cosmetics Alliance supports the proposed findings as outlined and will be submitting comments accordingly, in addition to providing some minor feedback to clarifying the reported use patterns regarding musk xylene. If you have any additional comments on the details as presented in the DSAR that may be relevant, please touch base with your Cosmetics Alliance Regulatory Team (regulatory@cosmeticsalliance.ca)!

Microbeads Laboratory Test Method Published

Environment and Climate Change Canada (ECCC) formally published their official Laboratory Test Method for Microbeads in Toiletries. In finalizing this method, ECCC has indicated that they have considered the significant feedback that Cosmetics Alliance (and other stakeholders) submitted in response to the embargoed draft method circulated earlier this year.

Although some of the input that Cosmetics Alliance provided has indeed been reflected in this final method, unfortunately, the most important and substantive of our observations remain outstanding; specifically:

- The scope of the analytes covered (many substances which are polymers but should not be considered plastic, let alone, microbeads)
- The possibility for introducing artefacts (i.e. solid particles that are not actually in formulation) into testing samples by virtue of the processing of samples

POSSIBLE IMPLICATIONS FOR MEMBERS

This test method is purported to be the analytical methodoloy that ECCC will use to ensure compliance and enforcement (C&E) with the *Microbeads in Toiletries Regulations* that came into force late last year. On this basis, we would expect that this will be the method that will guide any corresponding in market cyclic enforcement programs that ECCC may choose to pursue regarding products potentially subject to these Regulations.

Cosmetics Alliance remains extremely concerned that if implemeted as is, this method could result in significant **FALSE POSITIVES** concluding the presence of microbeads in sampled personal care products, thereby potentially leading to:

- Premature and unnecessary enforcement actions
- Inappropriate stigmatization of products
- Inaccurate and unacceptable critique of the relative effectiveness of both mandatory and voluntary risk mititgation efforts

All of this could result in significant business implications and potential threaten brand and/or product reputations, despite exercising all reasonable considerations to legitimately address and control the expressed "microbeads of concern" that is the underlying intent of ECCCs regulatory actions on microbeads.

WHAT COSMETICS ALLIANCE IS DOING TO ADDRESS CONCERNS

Working with our RAIS Committee, Cosmetics Alliance continues to pursue additional technical 'benchtop' analyses to supplement our continuing representations before ECCC on this file.

Our interventions at this juncture, have been with risk managers and technical representatives at ECCC with the hopes of influencing the technical drafting of this method. Unfortunately, we were not notified until after the fact of ECCCs finalization of this method.

We are now in the process of drafting a letter to send to the senior officials and to escalate accordingly to seek formal withdrawal and reprise from this method until such time as these concerns can be more comprehensively addressed. In presenting this follow-up letter, we will be reminding officials of the collective reputational benefit that this intervention would have for all parties. The last thing ECCC would need would be to invite crticism on their chemicals management program – in light of the on-going efforts regarding CEPA review and pending Auditor General's report on the effectiveness of the Government's CMP.

MEMBERS ARE ENCOURAGED TO CONSIDER THE FOLLOWING CONSIDERATIONS:

- Review Appendix 1 and 2 of the Test Method (method analytes) to understand what ingredients in your formulations could potentially be 'singled out' as "microbeads" should any of your products be subject to cyclic enforcement
- Prepare a formulation defense narrative that addresses why your formulas do not contain any "microbeads of concern" as per the original intent of the CEPA Schedule 1 Listing, specifically:
    - "Plastic Microbeads of concern are solid plastic particles that are less than or equal to 5 mm (in the largest external dimension) which are added to personal care products to exfoliate or cleanse the human body"
      [Final Order Adding "Microbeads" to the List of 'Toxic' Substances under EPA – Canada Gazette II, Vol. 150, No. 13, June 2016]

- Be prepared to challenge any findings of analytes that may have been introduced into samples as a result of processing (i.e. not in formula, but rather introduced into sample as a result of the processing of samples per the test method)
    - Leveraging the fact that these artefacts by definition would not be 'added" (i.e. not intentionally added to products; in fact, were not intended as part of the formulation, but introduced through sample preparation)

- Work with Legal Counsel (as appropriate) to identify key observations to reflect on (if challenged) regarding your approach to the management of "microbeads of concern" as per the underlying intent of the Regulations and the commitment as articulated by ECCC officials in representations before CA membership regarding their intent to model the scope of actions to be similar to those delivered in the corresponding US Fedral Legislation (i.e. product in Canada intent to meet both the Canadian and US regulatory construct – underpinning the legislative approaches taken in both jurisdictions)

NOTE: The above recommendations are not intended to be comprehensive, but rather are intended to initiate further dialogue. Furthermore, none of the observations outlined reflect legal advice of any kind. Members are encouraged to discuss any actions with their respective Legal Counsel in the event of any C&E activities that may implicate individual products/formulations.

If you have any questions or would like to discuss these developments in further detail, please do not hesitate to contact your Cosmetics Alliance Regulatory Team (regulatory@cosmeticsalliance.ca)!

Post-Consumer Waste Updates

Register for CSSA Annual Steward Meeting

The Canadian Stewardship Services Alliance (CSSA) will hold the 2018 Annual Steward Meeting (ASM) on Wednesday, October 24; 1 p.m. - 3 p.m. EDT. This year's event will be webcast only and supported by an enhanced web experience. The ASM, hosted by CSSA on behalf of the stewardship programs, provides stewards with updates on packaging and paper recycling program performance along with next year's program budgets and material fee rates. Register here.