Regulatory Essentials – February 6, 2019

Cosmetics Alliance Update

The Value of Membership – 2018 Highlights and Membership Renewal 2019

We need your involvement and commitment in order to help Cosmetics Alliance Canada advance the collective interests of the cosmetics and personal care products industry.

Please click here for CA's 2018 highlights with information about the Association's benefits and services, advocacy efforts, and the value of membership to you and your business.

Click here for the steps to renew.

Health Updates

Additional Information on the Expansion of the Sunscreen Pilot Update

After significant engagement with CA, Health Canada's Regulatory Operations and Regions Branch (RORB) has now addressed many of the issues identified by CA and our member companies following their initial announcement of the pilot's expansion. As outlined in their January 22nd DEL Bulletin #47, Health Canada's expanded Sunscreen Pilot includes:

- Expansion of foreign jurisdictions to include: Mexico, Japan, Australia, Switzerland, the European Community (EC) and the European Economic Area – European Free Trade Association (EEA-EFTA)
- Use of Regulatory Authority inspection reports outside their own jurisdictions, with conditions
- Use of corporate/consultant audit reports, with conditions
- Expansion to identity and confirmatory testing
- Expansion to include sunscreen products which are fabricated in Canada but may be packaged, labelled or tested in any of the jurisdictions included in the original or expanded jurisdictions
- Removal of the 5-year limitation on absence of US FDA or HC inspections and replacement with NERBy (New Evidence Required by Date)

These changes will become effective February 14th, 2019 and will allow participating companies to take full advantage of the pilot with significant savings in time, effort and costs. With this expansion now in place, CA will again take up our efforts for a further expansion to include all Category IV and oral care products. Stakeholders can start applying for the Expanded Pilot however application will be reviewed starting February 14, 2019 with a 10-day service standard.

The pilot was intended to provide some interim relief from inappropriate and unnecessary "drug" regulation for these types of low-risk drug (DIN) products as the larger classification issues are being addressed through the Self-Care Framework reform process.

DEL Bulletin – EN

DEL Bulletin – FR

Expanded Sunscreen Pilot Application Form – EN

Expanded Sunscreen Pilot Application Form – FR

Expanded Sunscreen Pilot Table – EN

Expanded Sunscreen Pilot Table - FR

NAFTA to CUSMA – Resolving the Long Standing Prohibition on Samples for Low Risk Health Products

As one of the first benefits for our industry under the new NAFTA is that Health Canada has recently advised stakeholders that elimination of the current prohibition on providing free samples of drug products to consumers will be addressed in the NAFTA implementation legislation for the low-risk "cosmetic-like" drug products identified in the Cosmetics Annex of the new NAFTA agreement.

This provision, which is the first ever in any trade agreement, recognizes that there are low-risk products that can be both "cosmetics" and "drugs", and as such should be regulated differently than "drugs" to more consistently reflect their risk and consumer use. These products include Category IV and oral care products such as sunscreens, anti-dandruff shampoos, and toothpastes.

Securing a Cosmetics Annex and the recognition of products at the "cosmetic-drug interface" was a major objective of CA and our fellow industry associations from the U.S. (PCPC) and Mexico (CANIPEC) in the year-long NAFTA negotiations. It was through our industry's persistence that this important recognition of "cosmetic-drug" products and the need for their appropriate regulation was achieved in NAFTA.

Under the new NAFTA, Health Canada will still be empowered to establish reasonable regulations around sampling but the outright prohibition will be eliminated. It is expected that the NAFTA implementation bill will be introduced into Parliament this spring and be passed before Parliament adjourns in late June. Regulations will then have to be developed.

It has long been an objective of all associations representing the broader range of drug products to replace this outright prohibition on "free sampling" with reasonable regulation. It is expected that the provisions negotiated by the cosmetics industry will provide a basis for the expansion of this reform.

Notice to Stakeholders of Proposed Updates to the Cosmetic Ingredient Hotlist

Health Canada has recently posted the proposed updates to the Cosmetics Ingredient Hotlist. The last update to the hotlist was in September 2018. Below is the proposed revision to existing entries on the hotlist.

Prohibitions:

1. **Dihydrocoumarin:** A revision is being considered to change this entry from a prohibition to a restriction. The ingredient is naturally occurring in some plant derivatives at low levels. A review of the available scientific data indicates that the ingredient may cause sensitization at higher concentrations but can be used at low levels without significant risk.
2. **Disulfiram, Thiuram, Thiuram disulfides, and Thiuram monosulfides**: A revision is being considered to combine these entries under a single entry for "Thiurams". This entry will also encompass thiuram tetrasulfides which are not presently captured under

the Hotlist entry. These substances have all been identified to pose similar skin sensitization risks. Revising the Hotlist entry from a prohibition to a restriction is also being considered because a review of the available scientific data indicates that the ingredients may cause skin sensitization at higher concentrations but can be used at low levels without significant risk.

Restrictions:

1. **Eucalyptus Oil:** A revision to the entry is being considered to better mitigate risk of accidental ingestion, particularly in pediatric populations.
2. **Sodium bromate:** A revision of the current restriction to a prohibition is being considered. Sodium bromate is toxicologically equivalent to potassium bromate, which has been prohibited since March 2011 due to its carcinogenic potential, as assessed by the Government of Canada's Chemicals Management Plan under the Canadian Environmental Protection Act, 1999.
3. **Thioglycolic acid and its salts:** A revision to the entry is being considered due to changes in ingredient usage. New conditions regarding hair products and products for use in the area of the eye will be considered.

The above-mentioned ingredients will undergo consultation in three months with a 60-day comment period. In the interim, Cosmetics Alliance will be reviewing these ingredients. We encourage committee to review the notice and let us know if you have any concerns. Cosmetics Alliance will be working with its Risk Assessment and Ingredient Safety Committee to provide comments. If you have any comments, please email your CA Regulatory Team.

Pause-the-Clock Proposal Webinar Presentation and Recording

On December 10, 2018 Health Canada held the Pause-the-Clock Proposal for Drug Establishment Licence Applications. The presentation and recording are available below. For questions related to the webinar, please contact the Drug Establishment Licensing Unit at: hc.del.questions-leppp.sc@canada.ca.

PTC Webinar Deck – EN

PTC Webinar Deck - FR

English Web Recording

French Web Recording

Health Canada Requests Feedback on Potential Impacts and Uses if Company Names were added to the Generic Submissions Under Review List

Health Canada wants to know the possible impacts and uses to stakeholders if company names were added to the list of generic submissions under review. Feedback on the public consultation will be collected between January 17,2019 and February 8,2019. Comments can be emailed to hc.opprs.enquiries-enquettes.bprse.sc@canada.ca. Health Canada is interested in feedback on the following questions:

- What would be the potential impact on you or your organization if the name of the sponsor (the company that filed the generic drug submission) were to be added to the List?
- Would knowing the name of the sponsor be useful to you?
  - If yes, how would you use the information if Health Canada began providing it?
  - If no, please explain why this information would not be useful to you?

Generic Submission Under Review List

Submissions Under Review List

Annual License Review Webinar Presentation and Recording

On January 14 and 17, 2019 Health Canada held the Annual Licence Review Webinar Presentation and Recording. Below is the copy of the webinar deck and recording. If you have any questions related to Annual Licence Review please email hc.del.alr-eal.lepp.sc@canada.ca.

ALR Webinar – EN

ALR Webinar – FR

English Web Recording

French Web Recording

Environmental Updates

Webinar on Chemicals Management Plan Activities and Substances on the Revised In Commerce List

Health Cana is hosting a webinar on an update to the Chemicals Management Plan activities and Substances on the Revised In Commerce List (R-ICL) on February 28, 2019 from 1 p.m. to 2:30 p.m. The invitation was sent to all stakeholders on the Revised ICL stakeholder mailing list. If you are not on the mailing list please email RICL-LRSC@hc-sc.gc.ca to sign up for the webinar and to get on the R-ICL mailing list. The objective of the webinar is to provide all stakeholders on the revised ICL stakeholders mailing list with an opportunity to hear and learn about the current activities and on-going work on substances listed on the R-ICL. Below is the draft agenda.

Draft Overview of the Agenda

- Key steps and accomplishments to date
- Publication of the Final Notice to terminate nominations to the In-Commerce List
- CEPA Section 71 survey results – Results, Analysis and Next Steps
- On-going risk assessments of substances on the R-ICL
- Planned publications summary
- Strategic objectives and policies that affect the R-ICL

A reminder notice which includes the WebEx Session internet link and meeting password, as well as a copy of the presentation will be sent out shortly prior to the scheduled date.

Prohibition of Certain Toxic Substances

Health Canada posted the Consultation Document on Proposed Amendments to the Prohibition of Certain Toxic Substances Regulation, 2012 which closes on February 18, 2019. This consultation document is intended to inform and solicit comments from stakeholders on a proposed regulatory approach to amend the Prohibition of Certain Toxic Substances Regulation, 2012. The proposed regulatory approach is to remove or provide time limits for exemptions for perfluorooctane sulfonate, its salts and precursors that contain one of the following groups: $C_8F_{17}SO_2$, $C_8F_{17}SO_3$ or $C_8F_{17}SO_2N$ (PFOS), perfluorooctanoic acid which has the molecular formula $C_7F_{15}CO_2H$, its salts and precursors (PFOA), long chain perfluorocarboxylic acids that have the molecular formula $C_nF_{2n+1}CO_2H$ in which $8 \leq n \leq 20$, their salts and precursors (LC-PFCAs), polybrominated diphenyl ethers (PBDEs) and hexabromocyclododecane (HBCD) to phase out the use of these substances. It is also proposed to prohibit the manufacture, import, use, sale and offer for sale of dechlorane plus (DP) and decabromodiphenyl ethane (DBDPE), and products that contain them, should their final screening assessment reports confirm that they are toxic under section 64 of the Canadian Environmental Protection Act.

Key Personnel Change in Environment and Climate Change Canada

There are some important changes with respect to leadership and governance related to the Chemical Management Plan (CMP) Post 2020 Project. Effective January 28, 2019, Julie Thompson, from the Science and Technology Branch at Environment and Climate Change Canada (ECCC) will be the Director General responsible for the renewal of CMP. Please join Cosmetics Alliance in congratulating Julie Thompson in her new role. We look forward to working with Julie in the future.

Microplastics Stand by Statement on Annex XV Dossier

The European Chemicals Agency released the Annex to the Annex XV Restriction Report – Proposal for a Restriction on January 11, 2019. Cosmetics Alliance (CA) is working with Cosmetics Europe (CE) Environment Task Force to review the assessment. CA will continue to engage with CE to support science and risk-based approaches. Please take the time to review the report and let your CA Regulatory Team know if you have any questions.

ECHA Report

ECHA Proposal Report

ECHA Proposal Report Standby Statement

Post-Consumer Waste Update

CSSA Ready to Report Webinars – February 26 and 27, 2019

The Canadian Stewardship Services Alliance (CSSA) is helping ensure stewards are ready to report their annual packaging and paper product (PPP) data in the We Recycle Portal by the May 31 deadline. There will be reporting webinars on February 26 and 27 -- the first is designed for new reporters and the second for more experienced reporters. However, stewards may choose to attend either or both webinars. The 90-minute sessions will begin at 1 p.m. ET and include plenty of time for questions and answers -- see below for registration details. A new interactive Materials Tool that helps identify correct reporting categories and an online tutorial for calculating material weights using averages have been developed -- both are available on

the 2019 Reporting Resources page on the CSSA website. Other resources include the latest versions of the Guidebook for Stewards and Steward Lists. Stewards are encouraged to login to the Portal soon and confirm their 2019 obligation so any issues can be resolved well before the deadline. Webinars take place 1:00 – 2:30 EST on Tuesday, February 26: New reporters - Click here to register; and Wednesday, February 27: Experienced reporters - Click here to register.