Regulatory Essentials – April 17, 2019

Cosmetics Alliance Update

Spring Regulatory Workshop is a Few Weeks Away!

Cosmetic Alliance Canada's Regulatory Workshops provide members with the opportunity to stay up-to-date and informed on "everything regulatory". You will not want to miss this opportunity to hear from government officials and Cosmetics Alliance staff first-hand on issues that will directly affect your business. Cosmetics Alliance will be hosting a Member Engagement Session at the end of the Workshop followed by a reception so be sure to attend for the whole day.

This year's colour theme is green. Join the fun and wear green.

Key Updates from:

- Consumer Product Safety Directorate (CPSD)
- Natural and Non-prescription Health Products Directorate (NNHPD)
- Regulatory Operations and Enforcement Branch (ROEB)
- Self-Care Framework Team
- Cost Recovery

Final Agenda

Register

Health Updates

NNHPD Releases Updated NHP MAP

On April 12, 2019, the Natural and Non-prescription Health Products Directorate (NNHPD) posted the updated Natural Health Product Management of Applications Policy (NHP MAP) and will be hosting a webinar next week.

Please register by close of business Thursday, April 18, 2019 for the webinar (details below)

Key changes include:

- Performance standard changed for Class I (60 calendar days) and Class II (90 calendar days) applications, to provide sufficient time to assess that monograph parameters are met prior to issuing a licensing decision;
- Improved predictability of licensing application review outcomes through explicit listing of refusal criteria, which include the refusal of applications submitted on paper form;
- Unsolicited information not accepted as part of the application review process, except under certain conditions; and
- More efficient use of Information Request Notices (IRNs)

NNHPD will be hosting a webinar on the following dates and times below to provide an overview of the key changes as well as to answer any questions that you may have.

French Webinar		English Webinar	
Date:	Wednesday, April 24, 2019	Date:	Thursday, April 25, 2019
Time:	11:00 am – 12:00 pm EST	Time:	1:30 – 2:30 pm EST

Please register by close of business Thursday, April 18, 2019 by emailing hc.nnhpd.consultation-dpsnso.sc@canada.ca with your information:

- Choice of Webinar (English or French)
- Your Name
- Your Title
- Your Organization

You can send in your questions regarding the NHP MAP to hc.nnhpd.consultation-dpsnso.sc@canada.ca. Cosmetics Alliance will also be sending questions regarding the NHP MAP to NNHPD in advance of the webinar. Please email your questions to regulatory@cosmeticsalliance.ca by Tuesday, April 23, 2019.

Health Canada Posts Forward Regulatory Plan 2019-2021: Self-Care Framework

Health Canada will update its approach to regulating self-care products based on extensive consultations over recent years. The Self-Care Framework will roll out in phases over the coming years:

Phase I – Targeting spring 2020: Introduce, for consultation, targeted amendments to the Natural Health Products Regulations to improve labelling of natural health products (NHPs). This proposal will require essential risk information to be presented in a standardized format, with minimum font size and black-on-white contrast, making it easier to read, understand and compare with that for other similar self-care products, such as non-prescription drugs, on store shelves. The use of plain language will also ensure that information on labels can be easily understood by Canadians.

Phase II – Targeting spring 2020: Introduce, for consultation, targeted amendments to the Food and Drug Regulations to introduce a risk-based approach to regulatory oversight for non-prescription drugs. These include: expedited pathways for lower-risk products. These changes are intended to align the oversight for non-prescription drugs with other self-care products of comparable level of risk.

Phase III – Targeting 2021: Introduce, for consultation, regulatory amendments to address: evidence standards for similar health claims, extending risk-based regulatory oversight, seeking additional powers for Health Canada, such as the ability to require a recall or label change for all self-care products.

Please take the time to visit the website as it contains more information on Regulatory Cooperation Efforts (domestic and international), Potential Impact on Businesses and Consultations.

Health Canada Posts Consulting Consumer on Self-Care Product Labelling: A Report on "What We Heard"

Health Canada is pleased to announce the Canada.ca web posting of the "Consulting Consumers on Self-Care Product Labelling: A Report on "What We Heard" https://www.canada.ca/en/health-canada/topics/self-care-products/what-we-heard-product-labelling.html that summarizes feedback received on improving NHP labelling during in-person public consultations held across Canada in July 2018. The services of Delaney & Associates were retained to facilitate the sessions and prepare the Report.

The feedback received and captured in this Report provides us with information about consumer perspectives and behaviours in selecting and using self-care products. Moving forward on the Self-Care Framework, we will continue to engage stakeholders, including Canadians. To this end, further consumer engagement sessions on self-care labelling perspectives and behaviours will be delivered in Fall 2019. Refer to the Self-Care Framework Canada.ca webpage to get further information on the Self-Care Framework and follow upcoming consumer engagement sessions.

Budget Implementation Act (Bill C-97)

The Government of Canada has introduced the Budget Implementation Act, 2019 which is a follow up to the 2018 Fall Economic Statement in which federal departments were tasked with conducting a regulatory review to find ways to enhance competitiveness and innovation. Included in the Act are provisions to amend the Food and Drugs Act to address three concerns:

1. Classification: This is to address process concerns to determine the classification of products that could fall within more than one product type under the Food and Drugs Act. It will allow the Minister to consult to determine how these things will be classified.

2. Clinical Trials: These provisions would address clinical trial processes for drugs, devices and food.

3. Advanced Technologies: This would allow Regulations to catch up to innovative and adaptive technologies, such as 3D printing, that are already being used, particularly in the medical device world.

Additional components of this regulatory review will be announced in coming months including to publishing of Regulatory Roadmaps by the Treasury Board.

Environmental Updates

Chemicals Management Plan Posts Various Draft Screening Assessments

Triazines and Triazole Group

The draft screening assessment of Amitrole (61-82-5), Sodium dichloroisocyanurate (2893-78-9), Hex(methoxymethyl) melamine (3089-11-0) was released on April 13, 2019. The draft screening assessment concluded that the substances did not meet any of the criteria of Section 64 of CEPA. The 60-day public comment period will send on June 12, 2019 and the Final Screening Assessment is anticipated to be released in April 2020.

Inorganic Substances of Low Concern

The Draft Screening Assessment for Substances identified as being low concern using the ecological risk classification of inorganic substances and three human health science approaches was published for a 60-day public comment period ending on June 12, 2019. The Final Screening Assessment is anticipated to be released in April 2020.

Cosmetics Alliance will be providing comments on the draft screening assessment based on members interest. If you have any questions or concerns please reach to your CA Regulatory Team at regulatory@cosmeticsalliance.ca.

Health Canada Releases Summary of Inventory Updates for 2017

A summary of the information received in response to the 2017 Inventory Update (chemicals and polymers) is available via the Government of Canada Open Data Portal. The information that the Government of Canada has collected for many substances may no longer represent current commercial activity in Canada. The government recognizes that maintaining an up-to-date inventory of substances in commerce is critical to informing risk assessment and risk management programs and activities.

To date, three inventory updates have been conducted under Canada's Chemicals Management Plan (CMP). The first two, in 2009 and 2012, focused on a subset of substances on the Domestic Substances List. The third inventory update, in 2017, surveyed substances on the Domestic Substances List, the Non-Domestic Substances List, and the Revised In Commerce List. It considered substances identified by emerging science, domestic and international regulatory programs as well as changes in Canadian commerce. Please visit the website to view the 2017 inventory updates.

Updated Science Approach Document for Substances with Low Human Health Hazard Potential was Released

The updated Science Approach Document for Substances with Low Human Health Hazard Potential was released. A science approach document (SciAD) provides a description of a scientific approach to evaluate environmental or human health risk of substances. SciADs also include the results of the application of the scientific approach to substances that were identified as priorities for assessment because they met the categorization criteria under section 73 of the Canadian Environmental Protection Act, 1999 (CEPA 1999) or were identified through other mechanisms as assessment priorities. The SciAD is published under section 68 of CEPA 1999, and does not include regulatory conclusions. A period of consultation on the SciADs is provided to the public as an opportunity to comment and provide additional information. The approach and results for substances identified as low concern in the SciADs will form the basis, in conjunction with any other relevant information that becomes available after the publication of the SciAD, for the conclusion in the screening assessment that will be published at a later time. This staggered approach, with publication of the scientific approaches and results in SciADs and subsequent publication of formal screening assessments, will assist the government in addressing substances that may be of low concern to either human health or the environment in a more effective manner.

Post-Consumer Waste Updates

Ontario MHSW Wind Up Plan Consultation – Comments Due May 1, 2019

The Webinar, presentation and Q&A documents from the April 2, 2019 webinar consultations are now available on the Stewardship Ontario (SO) MHSW Wind Up web page. Stakeholders

may provide feedback on the wind-up proposals by no later than Thursday, May 1, 2019, using one of the following methods:

- Email feedback to consultation@stewardshipontario.ca;
- Submit feedback via the online feedback form; or
- Mail feedback to Stewardship Ontario, 1 St. Clair Ave. W, Suite 700, Toronto, ON M4V 1K6.

Feedback will be considered as SO finalizes the proposed Wind Up Plan before submitting to the Resource Productivity and Recovery Authority (RPRA) by June 30, 2019. More information on the wind up of the MHSW Program can be found here.

See the previous Regulatory Essentials for full details on this Municipal Hazardous or Special Waste (MHSW) consultation. See also the Stewardship Ontario MHSW Wind Up web page. Questions may be emailed to consultation@stewardshipontario.ca.