Regulatory Essentials – August 4, 2021

Health Updates

COVID-19 SL Transition process and New Web-Based SLA Form

Important Notice to COVID-19 Site Licence Holders – 60 Day Notice and New Application Form

The Natural and Non-prescription Health Products Directorate has released their 60-day Notice for COVID-19 Site Licence Holders. Cosmetics Alliance and stakeholders have engaged with Health Canada on the transition process and what it should look like over the last number of months via surveys and stakeholder engagement sessions. As a reminder, COVID-19 Site Licence holders were afforded authorizations under an interim pathway to allow the import, manufacture, package, and label alcohol-based hand sanitizers using an expedited process with reduced evidential requirements.

If you are the holder of a COVID-19 Site Licence you are required to act before September 30th if you:

- wish to continue activities beyond September 30th
- do not wish to continue activities beyond September 30th
- have already stopped or never carried out activities

Should you not act before September 30th you are required to cease your activities affective at the end of September 30th. For details on these three categories see here

Health Canada has implemented a web-based application form for the Interim COVID-19 Site Licence transition pathway to enable stakeholders and Health Canada to process applications more efficiently for stakeholders wishing to continue activities beyond September 30th.

Health Canada has provided details on:

- The Interim COVID-19 SL transition process
- Supporting GMP evidence
- COVID-19 Site Licence Application Refusal Criteria

Health Canada releases version 2.0 of the Harmonized Site Licence and Foreign Site Reference Number Web-Based Application Form

The revised application form was released on July 24th to address several overall improvements to the form and to add a pathway for COVID-19 Site Licence to transition to full Site Licenses allowing for a more efficient application process for stakeholders and processing by Health Canada.

Cosmetics Alliance is pleased with the progress in enabling on-line systems for use by stakeholders. These on-line systems are an integral portion of the Self-Care Framework in enabling the concept of pre-cleared information (PCI) in making application processes more efficient for stakeholders and the regulator.

For details on how to transition from a COVID-19 Site Licence to a full Site Licence please click here.

For details on the overall improvements to the web-based form in general, please click here.

Update on Hydrocarbons INCI Name Change – Cosmetic Notification Form

Cosmetics Alliance notified members that PCPC has recently made changes for the INCI name of hydrocarbons (isoparaffins and pareths) on March 2, 2021. Further to the notice we have become aware that the Cosmetic Notification Form (CNF) says "not found" when the new name is searched. CA reached out to CHPSD and was informed that they are aware of the changes and their intent is to update the CNF with the new names. In the interim, stakeholders can use the new names as the Risk Assessment Group is aware of the name change and will process the form accordingly. If you do experience any challenges, please email regulatory@cosmeticsalliance.ca.

Important Changes at the Consumer & Hazardous Products Safety Directorate

Geoff Barret will be returning to his previous role as Director of Risk Management Bureau and John Fields has moved to a new role as Chief of the Chemical Health Hazard Assessment Division – Contaminants and Packaging under the Food Directorate. Jessica Roberts has taken over for John as the Acting Head of the Toxicology Unit under the Risk Assessment Bureau.

Publication of Single Ingredient High Dose Vitamin D Monograph

Further to the May 2021 stakeholder phone call, regarding single ingredient high dose Vitamin D submissions, the single ingredient high dose Vitamin D monograph was finalized and posted on Friday, July 23, 2021. Applicants can now submit single ingredient high dose Vitamin D submissions via Class I, using the Web PLA version 4 form. Other versions of the PLA form cannot be permitted.

The increase in Vitamin D was released as a single ingredient monograph due to the risks associated with higher dose of Vitamin D and to avoid the risk of combining high dose Vitamin D

with different ingredients. This was also done to increase awareness to Health Care Practitioners and consumers that higher doses of Vitamin D are available without a prescription.

For submissions that do not fall within the scope of the single ingredient high dose Vitamin D monograph will continue to be Class III submissions and this monograph cannot be combined with any other monographs as Class II submissions. Therefore, the only options available for high dose vitamin D products is to either submit via Class I or as a Class III.

Health Canada's Drug and Medical Device Highlights Report

The Health Products and Food Branch (HPFB) released the Drug and Medical Device Highlights Report on July 29, 2021. For Highlights and accomplishments for our industry on the area of Hand Sanitizers please click here.

Proposed Amendments Related to Agile Regulations for Licensing Drugs

On Saturday, July 31st, 2021, Health Canada released a notice proposing targeted amendments to the *Food and Drug Regulations* and *Medical Device Regulations* as part of the Phase 1 of the Agile Regulation Licensing Drugs Initiative. The Agile Regulations are part of the Forward Regulatory Plan 2021-2023 of which Self-Care Framework is an element but not part of this proposal which is Phase 1. This is the first phase of the Agile Regulations.

The proposed Phase 1 Agile amendments consists of four main components:

1. terms and conditions for all drugs and medical devices;
2. rolling submissions for drugs;
3. Risk Management Plans for higher risk drugs;
4. repeal of certain outdated provisions respecting biologic drugs.

Health Canada is conducting a cost-benefit analysis (CBA) survey to assess the potential impact of the proposed measures which can be found below. Cosmetics Alliance will monitoring the progress of these regulation and if you have any points for consideration please let us know at regulatory@cosmeticsalliance.ca.

Agile Regulation for Licensing Drugs CBA – EN/FR

Environmental Update

Order to apply the SNAc provisions of CEPA to Mitotane CASRN 53-19-0

Environment and Climate Change Canada (ECCC) released on July 21, 2021 the Order to amend the Domestic Substances List (DSL) applying the Significant New Activity (SNAc) provisions of CEPA to the substance benzene, 1-chloro-2-[2,2-dichloro-1-(4-chlorophenyl)ethyl]- (also known as “mitotane”, Chemical Abstract Registry Number 53-19-0), in the *Canada Gazette*, Part II. The final screening assessment published on October 28, 2017, concluded that mitotane may be harmful to the environment and meets the criteria under CEPA. As a result, it was added to the List of Toxic Substances (Schedule 1 to CEPA) on October 28, 2020. A risk management approach has been published concurrently and outlines the proposed risk management action to apply the SNAc provisions under subsection 81(3) of CEPA to mitotane.

Please note a significant new activity can include an activity that is not currently occurring or an existing activity involving a different quantity or occurring in different circumstances that could affect the exposure pattern of the substance for cosmetics and NHPs. No risk management actions are being proposed to limit the essential use of mitotane as a therapeutic drug. The Order requires any person that intends to manufacture, import, or use mitotane in the manner and quantity specified in the Order to provide prescribed information to the Minister of Environment at least 180 days prior to the commencement of the significant new activity. The Order outlines the information requirements, including a description of the new activity.

Please reach out to your CA Regulatory Team if you can any questions or concerns about this notice.