Regulatory Essentials – July 11, 2018

Health Updates

Revised Restriction and New Prohibition of Methylisothiazolinone in Cosmetics

It has come to Cosmetics Alliance's attention that Health Canada's Consumer Products Safety Directorate (CPSD) has begun issuing an "Industry Update Email" pertaining to methylisothiazolinone (MI) in cosmetics. This update follows the recent amendments to the Canadian Cosmetic Ingredient 'Hotlist', as published and circulated to members, June 2018 If you manufacture, import, distribute, wholesale or are otherwise responsible for cosmetic products that contain or may contain MI in Canada, *please review this important update*.

No transition provisions were included with the Final Amendment on June 14, 2018 (despite CA's recommendation to ensure that such provisions be clearly outlined). This has been the subject of CA's follow-up activities, as clearly it would be unreasonable for in-market products to be 'instantaneously put out of compliance' with this publication.

Only those members with products notified in the CNS as containing MI should receive this INDUSTRY UPDATE E-MAIL.

Members should consider this CPSD communique as an initial courtesy notice, to affirm awareness of these changes to the Hotlist.

Although corresponding compliance enforcement action may not be imminent at this time, members need to consider the following:

- Develop and implement a compliance action plan to address product compliance in light of this new guidance as soon as possible
    - Recommend that this plan reflect any proactive planning that members may have already been or are in the process of pursuing (since becoming aware of the original Notice, and certainly since earlier this year, when it was signaled that the proposal would be finalized as recommended)
    - Be prepared to proactively share details of these and corresponding commitments, as appropriate (either through a formal response to this Notice, or if/when asked)
    - If pursuing a formal response, recommend at a minimum (with the base objective to confirm awareness of these developments and commitment to compliance action as members deem adequate and appropriate)
        - Acknowledge receipt of e-mail
        - Confirm awareness of amendments and new guidance
        - Confirm intent to engage with appropriate compliance activities

- Submit, as appropriate, any updated notifications per Section 31 of the *Cosmetic Regulations* (statutory obligations), including
    - Notice of discontinuances for products no longer on market
    - Amendments reflecting product reformulations, as appropriate

- Establish a plan in consultation with vendors to clear pre-existing stock (thereby minimizing potential business losses)

- Be prepared to update existing product safety dossiers that leverage CIR assessment and existing post-market experience as evidence for compliance with the General Prohibition and justify an orderly transition to the revised guidance, as appropriate

- Follow-up with Cosmetics Alliance with input on what would be an appropriate, realistic and reasonable transition period to procure and/or update formulations and clear existing stock (see below).

  NOTE: *Given that Health Canada's e-mail is a courtesy notice, a formal response (outside of any statutory obligations, as outlined above) is not necessary. Any follow-up engagement would be at the discretion of individual members. Proactive engagement with Health Canada is encouraged, as this could build good will in line with the cooperative spirit that officials are seeking regarding these compliance activities.*

- CA will continue to pursue additional guidance for members providing greater certainty and predictability in transitional considerations, recognizing a tiered compliance approach, as outlined in our discussions with officials. This guidance will facilitate members' internal compliance activities and external interactions across the supply chain.

- In an effort to work collaboratively with officials, CA will be issuing a Member Survey to determine reasonable timelines to manage/update product portfolios and to clear existing stock from the marketplace. We encourage members to complete this survey to help ensure that we have a comprehensive understanding of transitional recommendations for HC to consider
- We will continue to work with CPSD to ensure that we are aware of and engaged in their follow-up compliance promotion activities. We will keep Members informed of any developments.

Drug and Medical Device Highlights 2017

Health Canada has recently developed a new form of communication regarding drugs and medical devices titled "Helping You Maintain and Improve your Health: Drug and Medical Device Highlights 2017. The purpose of this new communication is to inform stakeholders about new and innovative drugs and medical devices that have been approved for sale in Canada, risk communications that were published and other accomplishments in 2017. Cosmetics Alliance recognizes that this might not be relevant to most membership however this is provided as a FYI.

Publication of GMP Inspection Policy for Drug Establishments

The Heath Products Compliance Directorate has updated its "Good Manufacturing Practices Inspection Policy for Drug Establishments" (POL-0011). The policy has been updated to explain the inspection strategy currently in effect for GMP inspections of Canadian buildings that require a DEL and foreign buildings that must be authorized on DEL. This new version will help you better understand the inspection process along with the scheduling of inspections in Canada and abroad. The main objectives of this inspection strategy are to:

- minimize the health risks throughout the drug supply chain,

- assess through inspections the compliance of those that fabricate, package/label, test, import, distribute, or wholesale drugs with GMP requirements,

- take compliance and enforcement action when needed,

- maintain national consistency, and

- foster transparency with Canadians, industry, international regulatory partners, and other global stakeholders.

CA encourages member to review the updated GMP and let your CA Regulatory Team know if you have any questions.

GMP Inspection Policy for Drug Establishments – EN

GMP Inspection Policy for Drug Establishments - FR

Health Canada and United States Food and Drug Administration Joint Public Consultation on International Council for Harmonisation Guidelines

The Canada-United States (U.S.) Regulatory Cooperation Council (RCC) was created in February 2011 to better align the two countries' regulatory approaches, where possible. Under the RCC initiative, Health Canada and the U.S. Food and Drug Administration (FDA) are holding joint public consultation meetings on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines currently under development. The aim of this initiative is to hold public consultation meetings prior to each bi-annual ICH face-to-face meeting, to seek input on areas where harmonised ICH guidelines would be beneficial. Stakeholder input received through this initiative will be considered in current or future guideline development. Health Canada also intends to use these opportunities to better understand areas in drug product regulation where Canadian requirements may differ from those in place in the U.S., with a view to minimizing these differences.

The next ICH face-to-face meeting will take place from November 10-15, 2018 in Charlotte, North Carolina, USA. In preparation for this meeting, a public consultation for Canadian and U.S. stakeholders under the RCC initiative will take place on October 17, 2018 from 9:00 AM until 12:00 PM at the Sir Frederick G. Banting Research Centre, 251 Sir Frederick Banting Driveway, Ottawa, Ontario. Stakeholders will also be able to participate by webcast (information to follow). Registration is to be completed online.

Future consultations will continue to alternate between Canada and the U.S. with the next meeting (to be hosted by the U.S. FDA in the Spring of 2019 prior to the ICH meeting which will be held in June 2019).

A draft agenda follows. For additional information including Concept Papers and any available draft guidelines for comment please visit the ICH website.

In advance of the public meeting on October 17, 2018, Health Canada and the U.S. FDA are also offering the opportunity for stakeholders to submit comments in writing. Comments will be accepted from the date of this Notice until October 14, 2018.

Please submit comments to the following email address: HPFB_ICH_DGPSA@hc-sc.gc.ca

Draft Agenda

Health Canada – U.S. FDA ICH Consultation

October 17, 2018 – 9:00AM – 12:00PM

1. Opening Remarks/Introductions

2. Overview of the ICH Process

3. Overview of MedDRA and MedDRA Points to Consider

4. Overview of Current Efficacy Topics

5. Overview of Current Safety Topics

6. Overview of Current Quality Topics

7. Overview of Current Electronic Standards Topics

8. Closing Remarks

Environment Updates

Standing committee on Environment and Sustainable Development and Modernizing the Canadian Environmental Protection Act

On July 3, 2018 the Government of Canada released its Follow-up to the Government Response to the June 2017 Report of the Standing Committee on Environment and Sustainable Development and Modernizing the Canadian Environmental Protection Act. The Government agrees with many of the Committee's recommendations and has already addressed some of these recommendations through improved policy and program actions. This report also describes the many areas where the Government is committed to taking further action in the near-term. In addition, the Government will work towards legislative amendments as soon as possible in future Parliamentary sessions. Finally, there are a limited number of recommendations that the Government does not support. This report provides a rationale for each of these decisions. Please take the time to review the report.

Triclosan Added to Schedule 1 of the Canadian Environmental Protection Act

On July 11, 2018 Triclosan has been added to the Schedule 1 of the Canadian Environmental Protection Act (CEPA). Schedule 1 of CEPA includes substances that are considered to be toxic. The government of Canada completed a scientific assessment on triclosan and determined that the substance is entering or may enter in a quantity or concentration that have or may have an immediate or long-term harmful effect on the environment or its biological diversity and there meets the environmental toxicity criterion. Please take the time to review the notice and let your CA Regulatory Team know if you have any questions.

Post-Consumer Waste Updates

Ontario RPRA Authority – 2018 AGM Recording Available

The Ontario Resource Productivity and Recovery Authority (RPRA) held its Annual General Meeting on June 21, 2018. A recording is now available on RPRA's YouTube channel.

Ontario RPRA Registry – Tires Program

The Resource Productivity and Recovery Authority's Registry is officially open for Tire Producers and Producer Responsibility Organizations (PROs) at rpra.ca/registry per the Tires Regulation. The Registry Guide for tire producers, PROs and service providers, including collectors, haulers, retreaders and processors is also available.

Canadian Stewardship Services Alliance – 2017 Annual Reports

The recently published 2017 annual reports for Recycle BC , Multi-Material Stewardship Western (MMSW), Multi-Material Stewardship Manitoba (MMSM), Stewardship Ontario and Ontario's Automotive Materials Stewardship (AMS) are now available. The reports showcase each program's performance, financials, new recycling initiatives and accomplishments over the last year.