

## Regulatory Essentials – October 9, 2019

### Cosmetics Alliance Updates

#### Save the Date for Cosmetics Alliance Fall Regulatory Workshop

Cosmetics Alliance Fall Regulatory Workshop is around the corner! Save the date for December 12, 2019 at the Hotel Fairmont Chateau Laurier, Ottawa. You do not want to miss this event. Presentations will be provided from CPSD, NNHPD, ROEB and more! Registration will open next week with the agenda. Hope to see you all there!

### Health Updates

#### DEL Bulletin - Letter to market authorization holders of human pharmaceutical products to inform on steps to take to avoid nitrosamine impurities

Health Canada would like to notify you that as a precautionary approach, letters were sent to Market Authorization Holders (MAHs) of human pharmaceutical products requesting the evaluation of the risk of presence of nitrosamine impurities in human pharmaceutical products containing chemically-synthesized active pharmaceutical ingredients. The letters clearly outline information to MAHs on the steps and actions they should take.

Of note: the communication is intended for MAHs of human pharmaceutical products, including over the counter medications; it is not intended for MAHs of biologic, radiopharmaceutical, disinfectant, veterinary products or natural health products.

For reference, the letter is attached below. Cosmetics Alliance is following up with Health Canada to understand the scope of the notices. Membership will be updated on appropriate next steps in the coming weeks.

[MAH Letter – EN](#)

[MAH Letter - FR](#)

### Environmental Updates

#### Member Update – Preparing for Compliance Enforcement Microbeads in Toiletries Regulations

As a follow-up to the Microbeads in Toiletries compliance and enforcement update we outlined to members on [August 22, 2019](#), attached is a summary of key technical points regarding the limitations in scope regarding “microbeads of concern” and the definition of “toiletries” implicated. The key points outlined reflect representations that were made to officials in response to the August enforcement actions which have proven successful in keeping actions to the designated scope.

The attached document is an **internal** membership tool that CA Canada is sharing with our various relevant Technical Committees and our boarder membership to outline a standardize way to engage with officials should corresponding C&E come to the fore in the future. CA Canada highly recommends that our collective membership reflect on these key considerations to ensure consistent and coordinated follow-up to any such action, as appropriate. This document is circulated for internal membership use only and should not be circulated or distributed beyond this committee in any way without prior written consent by CA.

Please take the time to review the attached document. If you have any questions or concerns, please do not hesitate to reach out to your CA Regulatory Team.

### [Member Update Notice](#)

#### ECHA Assessment of Methyl Salicylate

The European Chemicals Agency (ECHA) on September 24 published a conclusion from the Committee for Risk Assessment (RAC) on [methyl salicylate](#). The RAS adopted the opinion that the substance is harmful if swallowed, may cause an allergic skin reaction, and is harmful to aquatic life with long lasting effects. The substance has also been classified as suspected of damaging the unborn child (rather than a higher-level “may damage the unborn child” designation as was proposed). Methyl salicylate has now been added to Annex IV of the *Classification, Labelling and Packaging Regulation* (CLP Regulation).

We would like to remind members that we are also expecting a Canadian Chemicals Management Plan (CMP) Groupings Assessment of salicylates. These European findings will be important as we review any Canadian assessment.

#### Post-Consumer Waste Updates

##### Stewardship Ontario's Proposed MHSW Wind Up Plan Submitted to RPRA

Stewardship Ontario has submitted its proposed MHSW Wind Up Plan to the Resource Productivity and Recovery Authority (RPRA) by the Minister's September 30, 2019 deadline.

RPRA is expected to post the proposed Wind Up Plan prior to its consultations with stakeholders -- please check the [RPRA](#) and [Stewardship Ontario](#) websites for updates. The Minister anticipates RPRA will approve the plan no later than December 31, 2019.

Upon wind up, materials collected under the MHSW Program will be managed according to an individual producer responsibility framework under the *Resource Recovery and Circular Economy Act, 2016*.

Please email [mhswwindup@stewardshipontario.ca](mailto:mhswwindup@stewardshipontario.ca) if you have any questions.