Regulatory Essentials – September 15, 2021

Health Updates

Update on the Self-Care Framework and Impact of the Upcoming Election

As you are aware Phase I: NHP Improved Labelling was published on June 26 with a 60-day consultation period as part of the phase in approach of the Self-Care Framework. With the upcoming election, Health Canada has taken on a 'care-taker' role and has extended the consultation period till September 24th. In the interim, CA is continuing to advocate for interim measures until the SCF is finalized. CA has been working through your PCMA and FCM Committees for possible interim measures until such time the Self-Care Framework has been implemented. If your company does not have representation on these committees or our other committees, please reach out to regulatory@cosmeticsalliance.ca for information on these committees and how to join.

GMP Certificates to Exempt Cosmetic Exports from China's Animal Testing Requirements

Cosmetics Alliance (CA) Canada has been engaging with Health Canada officials to allow for the importation of non-special cosmetics into China without the need for animal testing (i.e., animal testing waiver) through the use of a Health Canada-issued certificate. This certificate would be designed to meet what is presently understood to be the specific requirements for the exemption under Article 33 of China's *"Cosmetic Supervision and Administration Regulations"* (CSAR), particularly that such a certificate be government issued. At this juncture, it remains unclear as to the actual intent of the Chinese regulator as it is possible that these provisions are intended to ultimately protect domestic production in China as no exporting jurisdiction has yet been able to provide such a certificate that the Chinese authority has accepted as meeting the requirements of their regulation. Consequently, imported cosmetics essentially remain subject to animal testing in China. This proposed Health Canada certificate is being designed to clearly demonstrate products are manufactured to ISO GMP standards for cosmetics, or better, such that it will help to inform Canadian trade officials if a trade compliant is warranted.

Through CA efforts, Health Canada officials have notionally agreed in principle that the best plan of action would be to leverage existing Health Canada licensing activities for drugs and/or NHPs; or third-party auditing practices under applicable manufacturing standards for cosmetics as issued by the International Organization for Standardization (ISO).

CA's Formal Proposal, along with the proposed draft wording that would likely be reflected in any corresponding certificate issued by Health Canada, was shared with officials this past July/August for final legal and Ministerial review.

Unfortunately, officials have confirmed that they are presently operating under their "caretaker convention due to the upcoming election" [see correspondence below]. This convention puts on hold any formal interactions with stakeholders concerning legislative and regulatory policy

considerations under consultation or development. As a result, officials do not anticipate being in the position to discuss next steps until after the election on September 20, 2021.

In the interim, although we are aware that regulators in some jurisdictions have developed certificates or processes to address these provisions, we understand that all such certificates are presently 'under review' by the Chinese authority, and to our knowledge, none have yet to be formally approved. We are also aware that certificates issued by third parties with formal, legalized recognition by a reputable regulatory agency in the exporting country are being filed with the Chinese authorities; however, similarly, none of these to date have been considered acceptable at this time.

***Note**: CA Canada does work with Health Canada to issue GMP Certificates through our Certificates Program. We would be pleased to work with our members (or their clients, in the case of Contract Manufacturers) to issue such certificates; however, these GMP certificates are intended for generic manufacturing considerations, and we would clarify that it is unlikely that this will meet the specific criteria for a 'regulator-issued certificate', as per the provisions of Article 33 of the Chinese Regulations. That said, some of our members have elected to try to leverage these GMP Certificates on the off chance that, these would be deemed acceptable at some point. If this possibility is of interest to members, we would encourage you to get in touch with our Certificates Program.*

Post-Consumer Waste Updates

Blue Box Registration and Reporting is Now Open

Under the Blue Box Regulation, producers are required to register and report their 2020 supply data to the Authority on or before **Friday, October 1, 2021**. Producers will also be required to pay their 2021 Registry fee when submitting their 2020 supply data. Click here for more information and guidance on reporting.

2021 Registry Fees for Blue Box and Hazardous and Special Products Posted

The Authority has posted the final 2021 Registry fees for Blue Box materials and Hazardous and Special Products (HSP).

These are fees that producers obligated under the Blue Box Regulation and HSP Regulation under the Resource Recovery and Circular Economy Act, 2016 (RRCEA) are required to pay to the Authority in 2021. This is the first year that Blue Box and HSP producers are required to pay Registry fees to the Authority.

Other Updates

The Creme RIFM Aggregate Exposure Model

The Research Institute for Fragrance Materials, Inc. (RIFM.org) and Creme Global (Cremeglobal.com), a scientific modeling, data analytics, and computing company, partnered to develop an aggregate exposure model for fragrance materials (i.e., the total exposure coming from all different sources). This model looks at the exposure resulting from different fragrance materials used across various cosmetic, personal, household, and air care products. RIFM has used the model for more than six years to help refine the assessment of fragrance materials. As a result, it has substantially impacted the improvement of consumer safety of fragrances and the reduction of animal testing.

New Features and enhanced benefits for RIFM members

RIFM and Creme Global are now considering a simplified service agreement to allow more broadly based access to the model. The value of the Creme RIFM Exposure Model will be the same for all members — large and small fragrance manufacturers and consumer companies.

The model can help:

- Assess contaminant exposure & risk
- Understand new fragrance chemical exposures
- Identify exposures to residuals in the manufacturing process
- Demonstrate safe exposures to the consumer for various chosen geographies and population segments
- Provide insights on reformulations of both consumer products & fragrance mixtures based on simulating exposures under different use scenarios
- Provide marketing insights for all RIFM members by understanding the volume of products on the market & use profiles and the relative source contribution of different product categories (using Kantar World Panel data)

Coming soon: RIFM will sponsor **a series of webinars this September** to highlight the benefits of a subscription to the Creme RIFM Model. Meanwhile, learn more about the model by viewing this recently recorded webinar:

The Creme RIFM Aggregate Exposure Model