

Regulatory Essentials – August 29, 2019

Cosmetics Alliance Update

SmartLabel - Providing Consumers with Easy Access to More Information Than Could Ever

Fit on a Label: A Free Webinar

Join us on September 25th to learn more about how SmartLabel is changing what the future of labelling looks like in Canada and how it is allowing consumers to make more fully informed decisions.

This free webinar is designed to help companies understand:

- How SmartLabelling will increase e-commerce sales and how it can reduce inefficiencies and improve user experiences for e-retailers, logistics providers and consumers
- How SmartLabel™ Canada is designed to support the Canadian Drug Facts Table (eCDFT)
- Opportunities it can provide to Reduce Packaging sizes and how the technology is more environmentally sustainable
- Ways it offers consumers hundreds of product attributes, such as nutrition information and ingredients as well as facts that go well beyond the label

SmartLabel is a managed cooperation of Associations across Canada and the United States.

Many companies are already engaged and if your company isn't, this webinar is for you!

Date: September 25, 2019

Time: 1 – 2 p.m.

Presenter: [Jim Flannery](#)

To Register please RSVP mdavis@cosmeticsalliance.ca.

2019 Fall Regulatory Workshop – Date Change

As you may be aware, the Cosmetics Alliance Fall Regulatory Workshop was scheduled to take place on Wednesday, October 23, 2019 at the Fairmont Chateau Laurier, Ottawa. With the upcoming federal election taking place only 2 days prior, Cosmetics Alliance had preliminary discussions with government officials to gain insight on the potential limitations this could place on any presentations they would give.

Based on these discussions it was evident that government officials would only have been able to make limited remarks given the close proximity to the election. Even though the election would have taken place before the Workshop, there may be a change in cabinet members and ministers which will require swearings in, briefings by staff, and new mandates letters from the Prime Minister. As a result, we are moving the Workshop to Thursday, December 12, 2019, still at the Fairmont Chateau Laurier, Ottawa. This will allow time for the potentially new government to begin its mandate and the Workshop to keep its most valued component – open and transparent discussions with government officials. Going forward, this will not impact the dates

of future regulatory workshops. The Spring and Fall 2020 workshops are scheduled for May and October, respectively.

Registration information and a preliminary agenda will be sent out in early Fall. We hope to see you all in Ottawa this December.

Health Updates

New Deputy Ministers at Health Canada and Environment and Climate Change Canada

On August 23, the Prime Minister announced changes to the Deputy Ministers (DM) of both Health Canada and Environment and Climate Change Canada, the two key departments with which Cosmetics Alliance regularly engages.

Effective September 3, Simon Kennedy, current Deputy Minister of Health Canada, will become the Deputy Minister of Innovation, Science and Economic Development. Mr. Kennedy has held the role of DM of Health Canada since January 2015.

Stephen Lucas, currently the DM of Environment and Climate Change Canada will become the new DM at Health Canada on September 3 after almost three years at ECCC. He was previously the Director General of Health Canada's Health Products and Food Branch (HPFB) from 2003-2007. He has also held senior roles at Natural Resources Canada and the Privy Council.

Starting on September 30, the new DM of Environment and Climate Change Canada will be Christine Hogan who is currently an Executive Director at the World Bank. She has previously held executive roles within Environment Canada as well as the Privy Council, International Trade, and the Canadian International Development Agency (CIDA).

Cosmetics Alliance will be welcoming Mr. Lucas and Ms. Hogan to their new roles and look forward to working with them.

Important Emerging Developments – Enforcement Action: Microbeads in Toiletries Regulation

Environment and Climate Change Canada (ECCC) may be knocking on your door requesting access to samples and action regarding Microbeads in Toiletries Regulations.

As Cosmetics Alliance (CA) Canada members are well aware, the FULL prohibition regarding [Microbeads in Toiletries](#) (including both cosmetic products as well as natural and non-prescription products) has now come into effect, as of July 1, 2019. As previously reported, we anticipate that officials will at some point likely be kicking off a cyclic enforcement program following some rather aggressive and unprecedented compliance promotion initiatives that ECCC has been pursuing over the course of the past year (as highlighted in various corresponding highlights as published in Regulatory Essential).

We would like to advise our membership that yesterday, we were advised by one of members that they received a visit from ECCC Enforcement Branch expressing concerns that products in their portfolio contained microbeads and were therefore "out of compliance" with the Microbeads in Toiletries Regulations. In this regard, we understand that ECCC was looking to assert the following:

- Stop Ship Order for a list of products suspected of containing prohibited microbeads

- Request for submission of samples (for testing) for a list of products suspected of containing prohibited microbeads

IMPORTANT TO NOTE:

The majority of the products subject to this request were clearly OUTSIDE THE SCOPE of “microbeads of concern” as defined under the Final Order enabling the Microbeads in Toiletries Regulations, in that the products in question were not at all related to exfoliating or cleansing products. As recommended previously (see Regulatory Essentials Communiqués – June 14, 2017 and September 19, 2018; members-only website), members are encouraged to object to any scope of action that goes beyond the ‘microbeads’ of concern as reflected in the corresponding guidance to the Final Order (i.e. Regulatory Impact Assessment).

Specifically, “Plastic Microbeads of concern are solid plastic particles that are less than or equal to 5 mm (in the largest external dimension) which are added to personal care products to exfoliate or cleanse the human body” [Final Order Adding “Microbeads” to the List of ‘Toxic’ Substances under EPA – Canada Gazette II, Vol. 150, No. 13, June 2016]

Therefore, the request being made by the enforcement officers were NOT in line with the scope of their authority and should NOT be applicable to any such action.

WHAT MEMBERS NEED TO DO: BE PREPARED FOR A VISIT!

This is likely to be the first of many similar points of action – as we know officials are keen to pursue these compliance activities.

The process by which officials decide whether or not they visit your site is not clear; however, based on past precedent, you may be singled out because:

1. Compliant identifying a product attributed to your company as to ‘containing’ microbeads
2. Random on-shelf product audits by ECCC compliance officers
3. Random/partially random selection by ECCC based on a number of other factors

As recommended previously...

MEMBERS ARE ENCOURAGED TO CONSIDER THE FOLLOWING:

- Prepare a formulation defense narrative that addresses why your formulas do not contain any “microbeads of concern” as per the original intent of the CEPA Schedule 1 Listing, specifically:
 - “Plastic Microbeads of concern are solid plastic particles that are less than or equal to 5 mm (in the largest external dimension) which are added to personal care products to exfoliate or cleanse the human body” [Final Order Adding “Microbeads” to the List of ‘Toxic’ Substances under EPA – Canada Gazette II, Vol. 150, No. 13, June 2016]
 - Members are encouraged to review the list of substances that appear in the appendix to the “microbeads” [test method](#) as previously circulated to help identify substances that may be targeted (as previously reported September 19, 2018 – Regulatory Essentials)
 - Recall that bio-polymers that meet the definition of “microbeads” (per above) are NOT exempt; although members may wish to consider

providing evidence to justify that these uses would 'biodegrade' in aquatic environments and therefore should not be subject to these risk mitigation efforts

- Work with Legal Counsel (as appropriate) to identify key observations to reflect on (if challenged) regarding your approach to the management of "microbeads of concern" as per the underlying intent of the Regulations and the commitment as articulated by ECCC officials in representations before CA membership regarding their intent to model the scope of actions to be similar to those delivered in the corresponding US Federal Legislation (i.e. product in Canada intent to meet both the Canadian and US regulatory construct – underpinning the legislative approaches taken in both jurisdictions)
 - For members who have attended the multitude of CA Canada/CCTFA Regulatory or PCPC Workshops over the course of the past three or so years, whereby this topic has been addressed many times; recall that the key message from ECCC policy representatives was that the intent of this action was to be 'consistent and in-line' with the scope of action as per the US Microbeads Free Waters Act – which is also intended to be limited to microbeads used to exfoliate or cleanse the human body.
- Recall, in the consultation leading up to the finalization of the "Listing Name" ultimately reflected under Schedule 1 of CEPA, officials made it clear to CA Canada that this Schedule was a "list of substances" and as such, it was not in their purview to include 'functionality or use' to further qualify this listing. This is the reason why we and other parties insisted that these details be integrated in corresponding policy guidance (i.e. explanatory note, specifically outlining the "microbeads of concern" subject to the Order)

NOTE: The above recommendations are not intended to be comprehensive, but rather are intended to initiate further dialogue. Furthermore, none of the observations outlined reflect legal advice of any kind. Members are encouraged to discuss any actions with their respective Legal Counsel in the event of any C&E activities that may implicate individual products/formulations.

IF YOU RECEIVE A VISIT IN THIS REGARD – PLEASE LET US KNOW (e-mail: regulatory@cosmeticsalliance.ca)

In the interim, we will be looking to work with ECCC officials to clarify and manage the scope of these actions to those "microbeads" of concern as intended to be subject to this regulatory action.

If you have any questions or would like to discuss these developments in further detail, please do not hesitate to contact your Cosmetics Alliance Regulatory Team (regulatory@cosmeticsalliance.ca)

Important Update on Titanium Dioxide as a Non-Medicinal Ingredient in Sunscreens

We wish to update you on recent developments on the restriction currently listed in the Natural Health Products Ingredient Database (NHPID) for Titanium dioxide as a Non-Medicinal Ingredient (NMI) in sunscreens and the resolution we have reached with the Natural and Non-Prescription Health Products Directorate (NNHPD) on this file.

Currently the NHPID lists Titanium dioxide for topical use as an opacifying agent and colour additive but is not permitted in sunscreens (primary and secondary).

We have received confirmation from the NNHPD that until this TiO₂ restriction has been consulted upon, the NNHPD will maintain a status-quo, with TiO₂ being acceptable as an NMI in sunscreen products as an opacifying agent and colour additive. Correspondingly, we understand that this restriction will not be enforced during submission review at this time, and that further stakeholder consultations will be pursued should this status change in the future.

WHAT THIS MEANS:

- For any sunscreen applications for which you **have filed and received a rejection** because you listed TiO₂ as a NMI, you may re-file these applications (please reach out to regulatory@cosmeticsalliance.ca if you fall into this category as our understanding from the NNHPD is no applications have been rejected to-date and we have been asked to confirm this from our members).
- For any sunscreen **applications in queue**, you should not receive any questions or be rejected if you have listed TiO₂ as a NMI on your application.
- For any **new application**, you may proceed with filing these applications and expect no questions regarding the listing of TiO₂ as a NMI in your application.
- For existing products, there is no need to adjust your formulations at this time. If you have become aware of the restriction in the NHPID and have begun re-formulating or re-configuring your products because of this change, please notify us at regulatory@cosmeticsalliance.ca.

Should you have experiences contradictory to the above, please notify Cosmetics Alliance so we can facilitate a follow-up with the NNHPD.

NEXT STEPS

We appreciate that the NNHPD has informed us of this change prior to dropping of the writ of election. They have requested information from Cosmetics Alliance and our membership, which we will be sharing with you in the coming days. We will be managing the consolidation from this input through our Product Compliance & Market Access Committee. This information will assist them in better understanding industry practices, the role of TiO₂ as a NMI versus medicinal ingredient in sunscreen products, as well as the scientific rationale for its use for different purposes. This information will facilitate any future revisions to the NHPID entry for TiO₂ such that industry may continue to formulate products in a manner that meets the intent of the *Food and Drugs Act* and its regulations.

The NNHPD remains committed in this fiscal year to publishing the NHPID guidance that was originally consulted on as part of the Management of Applications Policy (MAP) last summer. The NHPID portion of the MAP consultation document was removed due to the complexity of the issue and the need to implement the MAP for the other elements.

Agile Regulations for Advanced Therapeutic Products and Clinical Trials

As reported in July 31 Regulatory Essentials (<https://www.cosmeticsalliance.ca/agile-regulations-advanced-therapeutic-products-clinical-trials/>), Health Canada is seeking feedback on what they should consider in developing new clinical trials regulations as well as implementing the pathway for Advanced Therapeutic Products. Health Canada has issued a reminder that these comments are due at midnight (Pacific Daylight Time) on Friday, August 30th.

Environmental Updates

Electronic Submission under the Environmental Emergency Regulations 2019

Environment and Climate Change Canada (ECCC) would like to inform companies that any information they are obligated to submit to the Minister under the *Environmental Emergency Regulations, 2019*, must be submitted electronically. Starting August 24, 2019 all information required under the *E2 Regulations, 2019* must be submitted in the new online E2 reporting system, accessed through the Single Window Information Manager (SWIM) (<https://ec.ss.ec.gc.ca>). This new electronic reporting system will replace the old E2 reporting system that will no longer be available at the same date mentioned above.

For guidance on how to report using the Environmental Emergency reporting system, refer to the Online Reporting System Guidance for the *E2 Regulations, 2019*, available through the programs website (<https://www.canada.ca/en/environment-climate-change/services/environmental-emergencies-program/regulations.html>), under “Environmental emergency regulations: filling a notice”.

ECCC reminds current regulatees of their obligation, under the Transitional Provision in Section 22 of the *E2 Regulations, 2019*, to resubmit the required information into the new E2 reporting system, which is required considering significant changes to the Regulations and new online E2 reporting application. Also, ECCC would like to advise that they are in the final stages of publishing the Technical Guidelines for the *Environmental Emergency Regulations, 2019*, which is expected to be published in the fall of 2019.

Chemicals Management Plan Stakeholder Advisory Council

An updated Chemicals Management Plan Stakeholder Advisory Council members list has been published. To view the updated list please click [here](#).

The Government of Canada Supporting small and medium-sized business through the Low Carbon Economy Fund

Today, the Minister of Environment and Climate Change, Catherine McKenna, announced up to [\\$10 million from the Partnerships stream of the Low Carbon Economy Fund](#) to support projects that reduce greenhouse gas emissions for small and medium-sized businesses with up to 499 employees. The Partnerships stream will help businesses across the country cut pollution through projects like retrofits, methane capture in municipal waste, switching to cleaner fuels and more efficient business operations, or greener ways to heat or cool existing buildings. Businesses will have until November 15, 2019 to apply.

The funding comes from the Government of Canada’s Low Carbon Economy Fund—an important part of Canada’s climate plan. The Fund invests in projects that reduce carbon pollution, save money, and create good jobs in a clean economy.

By working together with Canadians across the country and supporting good projects that offer practical and affordable solutions, we can continue to protect the environment and grow the economy for future generations.

Quick Facts:

- According to Clean Energy Canada, the energy efficiency measures in Canada's climate plan will help improve Canada's economy and environment between now and 2030 by creating 118,000 new jobs, boosting our GDP by \$356 billion, and saving Canadian households an average of \$114 a year. Every \$1 spent on energy efficiency generates approximately \$7 of GDP.
- The Low Carbon Economy Challenge is part of the Low Carbon Economy Fund and supports projects that will leverage ingenuity across the country to reduce emissions and generate clean growth. The Low Carbon Economy Challenge has two streams:
 - Champions stream: with over \$450 million available, this stream provides funding to eligible applicants including provinces and territories, municipalities, Indigenous communities and organizations, businesses and not-for-profit organizations. The deadline for submitting formal proposals was September 28, 2018.
 - Partnerships stream: with \$50 million available, this stream will provide funding through two separate opportunities:
 - First intake: Approximately \$40 million for projects led by Indigenous communities and organizations, small and medium-sized businesses, not-for-profit organizations, and small municipalities. The deadline for submitting proposals was March 8, 2019.
 - Second intake: Approximately \$10 million for small and medium-sized businesses in Canada with up to 499 employees. The application process will be open from August 13 to November 15, 2019.

Post-Consumer Waste Updates

Ontario's Blue Box Program: New Direction Letter

On August 16, 2019 the Ontario Minister of the Environment, Conservation and Parks (MECP) and the Minister of Municipal Affairs and Housing announced the next steps for transitioning the costs of the Blue Box Program away from municipalities, making the producers of products and packaging fully responsible. Based on recommendations from Special Advisor David Lindsay's [report](#) on Recycling and Plastic Waste, Blue Box services will transition to producer responsibility in phases over a **three-year period, starting January 1, 2023**. By December 31, 2025, producers will be fully responsible for providing Blue Box services province-wide. Environment Minister Yurek has directed Stewardship Ontario to develop a plan pursuant to section 14 of the *Waste Diversion Transition Act*, which will outline how the current program would be operated during the three-year transition period. Stewardship Ontario must submit the plan to the Resource Productivity and Recovery Authority (the Authority) no later than **June 30, 2020**. It is expected the Authority will approve the plan no later than **December 31, 2020**. Transitioning the Blue Box Program to producer responsibility will be a multi-stage process that will involve many opportunities for stakeholder input. To view the direction letter, visit the Authority's website at <https://rpra.ca/blue-box-transition/>.

MHSW Wind Up Plan Feedback: Due Friday, August 30, 2019

Stewardship Ontario (SO) held Phase II consultation webinars on the Municipal Hazardous or Special Waste (MHSW) Wind Up Plan on August 14 and 20, 2019. The webinar replays and presentation are available [here](#). Feedback is requested by SO by no later than Friday, **August 30, 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 help SO as they finalize their proposed Wind Up Plan before submitting to the Resource Productivity and Recovery Authority by September 30, 2019.