

## Regulatory Essentials – June 5, 2019

### Cosmetics Alliance Update

You and Your Company are invited to participate in a CA-Health Canada **Symposium on Self-Care: The Canadian Experience** on Friday, July 12<sup>th</sup> from 9:00 am to 12:00 pm at the Hotel Omni Mont-Royal (1050 Sherbrooke St W, Montreal).

In conjunction with an international meeting of cosmetic regulators, Health Canada with Cosmetics Alliance are hosting a symposium to present the "re-think" in the way in which self-care products – cosmetics, natural health products, and non-prescription drugs – are regulated in Canada.

**This “once-in-a-lifetime” reform** is expected to place Canada as a leader in the world and the ability to innovate in our sector.

What Canada is doing, and the lessons learned, are attracting significant attention from regulators and industry from around the globe.

Here is your opportunity to hear from the Self-Care Team who are leading this important initiative!

You are sure to find the Symposium of **great interest to you and the future of your business.**

Attending the symposium will be **international cosmetic regulators** from the European Union, the United States, Japan, Brazil, Canada and a host of observer jurisdictions who will be gathering in Montréal for the annual meeting of The International Cooperation on Cosmetics Regulation (ICCR).

This event brings together regulators, industry and other stakeholders who together represents well over half of the world’s cosmetics market. It provides a forum to coordinate regulation to both provide the highest level of product safety, as well as alignment which can facilitate international trade. ICCR recommendations often become the “international standard” for our products globally. Here is your **chance to network with these important leaders in regulation.**

To register yourself or any interested colleagues in your company, please contact Michele Davis at [mdavis@cosmeticsalliance.ca](mailto:mdavis@cosmeticsalliance.ca) or 905-890-5161 ext 229. There is also a hotel block available.

Seating is limited, so don’t delay in registering.

**This is a Complimentary Event.** There is no registration fee.

### Health Updates

#### Performance Standard for the Fees in Respect of Drugs & Medical Devices Order

The purpose of this document is to provide the performance standards to be used to determine whether a remission should be granted, under the Fees in Respect of Drugs and Medical Devices Order (Order), to a person who must pay a fee under that Order.

The Guideline on Service Standards developed by the Treasury Board of Canada Secretariat defines a service standard as follows: a service standard is a public commitment to a measurable level of performance that clients can expect under normal circumstances.

Further to consultations from October 2017 to June 2018, Health Canada has established the following performance standards in relation to fees that are payable under the Order. The standards appropriately reflect the Department's ability to deliver its service(s) within a set timeframe.

For the purposes of the [Fees in Respect of Drugs and Medical Devices Order](#), to come into force on April 1, 2020, below are the performance standards applicable to fees for drugs and medical devices. Please note the [Performance Standards](#) will be implemented on April 1, 2020, whereas, the Guidance for Industry: Management of Drug Submissions reflects current practices. All Guidance Documents will be updated closer to implementation.

### [Final Report: Fees for Drugs and Medical Devices](#)

#### [Cost Benefit Analysis Survey Webinar Slides](#)

On May 23, 2019 Health Canada hosted a webinar on the Cost Benefit Analysis Survey. The slides for the presentation are below. Please note the survey is due by July 10, 2019 to Health Canada.

#### [CBA Webinar Deck – EN](#)

#### [Publication of the Revised Bundle 9 Monographs to Address Statements to the Effect Of](#)

The Natural and Non-prescription Health Products Directorate (NNHPD) updated the following monographs to reflect the changes to the "Statements to the Effect Of"

1. 3,3'-diindolylmethane (DIM)
2. African Wild Mango
3. Alfalfa
4. Alpha lipoic acid
5. Bearberry
6. Beta-Glucan
7. Blueberry
8. Citrus Bioflavonoids
9. Digestive Enzymes
10. Dong quai - Angelica sinensis
11. Free Plant Sterols
12. Goldenseal - Buccal
13. Goldenseal - Oral
14. N-Acetyl-L-Cysteine
15. Quercetin
16. Stinging Nettle
17. Stinging Nettle- Juice
18. Taurine
19. Theanine, L-
20. Tyrosine, L-

Please visit [What's New Page](#) to find a listing of modifications to the Natural Health Products Ingredients Database (NHPID) since the last update.

## **Environmental Updates**

### **Draft Screening Assessment of Siloxanes Group**

The [Draft Screening Assessment of Siloxanes](#) was published on June 1, 2019 with a 60-day public comment period ending on August 1, 2019. The final screening assessment is expected to be published in June 2020. There are six substances being assessed which can be found below.

<b>Substance group</b>	<b>CAS RN</b>	<b>Common name</b>	<b>DSL name</b>
<a href="#">Siloxanes Group</a>	107-46-0	Hexamethyldisiloxane (L2)	Disiloxane, hexamethyl-
	141-62-8	Decamethyltetrasiloxane (L4)	Tetrasiloxane, decamethyl-
	141-63-9	Dodecamethylpentasiloxane (L5)	Pentasiloxane, dodecamethyl-
	541-05-9	Cyclotrisiloxane (D3)	Cyclotrisiloxane, hexamethyl-
	2627-95-4	Divinyltetramethyldisiloxane (dvTMDS)	Disiloxane, 1,3-diethenyl-1,1,3,3-tetramethyl-
	69430-24-6	Cyclomethicone	Cyclosiloxanes, di-Me

The 6 substances in the Siloxanes Group are associated with some health effects; however, the risk to human health is low. They are also considered to have a low potential to cause ecological harm. Therefore, it is proposed that these substances are not harmful to human health or to the environment at current levels of exposure. Of importance is the Cyclomethicone which a blend of D4, D5, D6 and linear siloxanes which has been determined to be low risk to humans. This is a good example of the reasonable approach taken towards CMP assessment as these substances are restricted for use in the European Union. Please take the time to review the DSAR and if you have any concerns please email [regulatory@cosmeticsalliance.ca](mailto:regulatory@cosmeticsalliance.ca). CA will be commenting based on members interest.

### **Canada to Help Small Businesses Invest in Energy-Saving Equipment and Retrofits**

Recognizing that small businesses are the backbone of the economy, the Government of Canada has reduced the small business tax rate to nine per cent, making it the lowest among G7 countries. The Government is making significant new investments to help small and medium-sized businesses reduce pollution, save energy and boost their productivity.

The Minister of the Environment and Climate Change, Catherine McKenna, announced [two new proposed programs](#) that will help owners of small and medium-sized businesses be more energy-efficient, save money, and take action to reduce pollution. These programs are subject to passage of the Budget Implementation Act and subsequent specifications by the Minister of Finance.

Under the Climate Action Incentive Fund, a portion of federal fuel charge revenue from Saskatchewan, Manitoba, Ontario, and New Brunswick will be used to support small and medium-sized businesses in these provinces, such as restaurant owners, farmers, truck drivers, and convenience and grocery store owners. Specifically, these businesses could be eligible for:

- Refunds between 25% and 50% on the cost of new energy-saving equipment -such as appliances, which could include appliances, heating and cooling equipment, anti-idling devices and high efficiency boilers;
- Funding of up to 25% of eligible costs for energy-efficient retrofits and other projects to improve energy efficiency, reduce their energy use and save money.

These investments will help make small and medium-sized businesses be more productive and competitive as they reduce their energy costs.

The Government is also establishing an External Advisory Committee, which will provide practical advice to help refine and improve the ongoing delivery of Climate Action Incentive Fund programs for small and medium-sized businesses.

In addition, the Government will open shortly a new call for proposals for smaller projects from small businesses across the country under the Low Carbon Economy Fund Partnerships stream. Approximately \$10 million will be available to help those businesses make investments to improve energy efficiency, reduce pollution and save money.

### Canada to host the 2020 World Circular Economy Forum

The Minister of Environment and Climate Change, Catherine McKenna, and the Minister of Innovation, Science and Economic Development, Navdeep Bains, today announced that Canada will host the [2020 World Circular Economy Forum \(WCEF2020\)](#), in partnership with Finnish Innovation Fund, Sitra. Canada has already started building a circular economy that benefits people, the economy and the environment.

The WCEF2020 will be the first large-scale international event to bring circular economy leaders to North America. It will be an opportunity for Canada to showcase its talent on the world stage. Canadian innovators will work with international counterparts to find new opportunities and ground-breaking solutions that can transform would-be landfill into new products and new business opportunities. Working together, Canada and its partners will build strong, sustainable economies at home and abroad.

A circular economy moves away from a “take, make and dispose” way of doing business to one where goods are produced, distributed, and consumed in a way that retains the value of products and resources for as long as possible. Canadians are seizing the opportunity and new policies are beginning to support the circular economy, accelerating our transition.

At WCEF2020, Canada will bring together business and thought leaders from around the world, sharing ideas about how, together, innovative product design and business models will help us

reuse and remanufacture materials, and create new economic opportunities, creating the clean jobs of the future.

CA will be monitoring developments and will be looking to engage as appropriate. Please reach out to your CA Regulatory Team if you have any questions.

### **Post-Consumer Waste Updates**

#### **Save the Date - CSSA Annual Steward Meeting**

The Canadian Stewardship Services Alliance (CSSA) 2019 Annual Steward Meeting is scheduled for Thursday, October 24 at 2:30 p.m. ET. Based on steward feedback, the meeting will be a webinar event again this year. Invitations and details will be distributed in late summer.