

## **Regulatory Essentials – March 4, 2020**

### **Cosmetics Alliance Update**

#### **2020 Spring Regulatory Workshop – Register Today**

Cosmetic Alliance Regulatory Workshops provide members with the opportunity to stay up-to-date and informed on "everything regulatory". Hear from government officials and Cosmetics Alliance staff on issues that will directly affect your business.

Important topics that will be covered:

- SCF – Phase I & II
- Update on Hotlist review process and ingredient prioritization
- Sunscreen Pilot & Expansion
- Cannabis Health Products Consultation
- DEL Updates – Performance & “Future Performance Standards”
- Update on Pollution Prevention notice for Triclosan
- Update on the 2020-2021 Information Gathering Initiative
- Sampling under CUSMA

There will be a Member Engagement Session at the end of the Workshop followed by a reception. Don't miss the chance to network, ask questions and to join the dialogue!

[Register](#)

### **Health Updates**

#### **Health Canada System Wide Outage Update**

Cosmetics Alliance has become aware the following Health Canada systems have not been functioning since late last Friday:

- NHPID
- w-PLA
- LNHPD
- DPD
- PLAN
- eCTD Gateway

Additionally, the Justice Canada – Justice Laws Website is not functioning. We do not know the extent of the canada.ca website outages, but are expecting some messaging for stakeholders from Health Canada shortly. We will share that communication with you once we receive it and will update our membership accordingly.

#### **NNHPD Multi-Lateral Summary & Materials**

Cosmetics Alliance attended NNHPD Multi-Lateral Meeting on February 4, 2020 in Ottawa. Beta Montemayor, Richard Parcels (Cosmetics Alliance) and Margaret Turnbull (Colgate-Palmolive) attended the meeting. Some important topics that were covered were:

- Update on the NHP online Solutions (NHPOLS)
- Implementation of the Management of Applications Policy

- Update on the Self-Care Framework
- Overview and results of the NHP Good Manufacturing Practices Compliance Monitoring Program and Quality Audit

Cosmetics Alliance will be debriefing the Product Compliance & Market Access (PCMA) Committee on March 4, 2020 on the important updates and learnings from the Multi-Lateral. If you would like to be on the call, please join the PCMA committee by emailing [regulatory@cosmeticsalliance.ca](mailto:regulatory@cosmeticsalliance.ca). For your reference please find below the NNHPD Multi-Lateral Presentation.

#### [NNHPD Multi-Lateral Presentation – EN](#)

#### DEL Bulletin No. 69 – Small Business Training Session – Revised Fees for Regulatory Services

As of April 1, 2020, Health Canada will be implementing revised fees for regulatory services related to drugs and medical devices. In addition, Health Canada will be modifying its existing fee mitigation measures to introduce a comprehensive Small Business Strategy.

Under the Small Business Strategy, companies that meet the Treasury Board of Canada Secretariat's small business definition will qualify to receive fee reductions. The definition is: *“Any business, including its affiliates, that has fewer than 100 employees or between \$30,000 and \$5 million in annual gross revenues”*. For businesses that qualify, Pre-market Evaluation fees will be reduced by 50% of the newly revised fees, and Right to Sell fees as well as Establishment Licence fees will be reduced by 25% respectively. For businesses filing their first ever Pre-market product submission, the fee will be waived. Note that this offer is only valid for new companies making their first ever submission; all subsequent submissions will be subject to the fee reductions listed above.

To benefit from the fee reductions, businesses must meet the definition above at the time of filing a drug or medical device submission, application or notification. Businesses must also indicate that they are requesting small business reduction on their Fee Form or VHP application portal. New businesses should specify that this is their first Pre-market evaluation submission ever filed with Health Canada.

Since this will be a new process for stakeholders, Health Canada will be hosting training sessions on the Small Business application process in both French and English. These training sessions will be held on March 11, 2020. The English session will run from 10:30 a.m. to 12:30 p.m. (EDT) and the French session will run from 1:30 p.m. to 3:30 p.m. (EDT). If you would like to attend English session, please use the following link to confirm your participation: <https://www.eventbrite.ca/e/95233242191>. To attend the French session, please register using this link: <https://www.eventbrite.ca/e/95242696469>. Meeting materials will be distributed to those who confirm their participation prior to the training sessions. After reviewing the meeting materials, you may submit questions in advance to be addressed during the session.

If you cannot attend the session, please contact [hc.sbo-bpe.sc@canada.ca](mailto:hc.sbo-bpe.sc@canada.ca) to request the recording of the presentations and meeting materials, which will be provided to you after the training sessions.

## Health Canada's Cannabis Panel – Request for Nominations

Thank you to all those who attended Cosmetics Alliance Cannabis Task Force: Scoping & Strategic Engagement Session last week. As discussed in the meeting, Health Canada will be establishing a new Science Advisory Committee for Health Products containing Cannabis. The Committee will provide independent scientific and clinical advice to support the Department's consideration of appropriate safety, efficacy and quality standards for non-prescription health products containing cannabis. Advice provided by the Committee will help to inform Health Canada's policies and a potential regulatory approach. As a trusted partner Health Canada has reached out to Cosmetics Alliance to nominate a representative for the personal care products industry. CA is looking for a representative that can provide technical expertise on cannabis in this panel. Please send in your nominations to [regulatory@cosmeticsalliance.ca](mailto:regulatory@cosmeticsalliance.ca) by no later than Monday, March 9, 2020.

In the interim, CA will be drafting the ToR for the Cannabis Task Force which will be sent to interested members at the end of March.

## **Environmental Updates**

### Fees Adjustment for the New Substances Program for 2020-2021

Environment and Climate Change Canada (ECCC) is adjusting fees for new substances notifications filed under the *New Substances Notification Regulations* (Chemicals and Polymers). ECCC is implementing this fee adjustment for the New Substances Program to be in compliance with Canada's *Service Fees Act* which requires annual fee adjustments based on the percentage change over 12 months in the April All-items Consumer Price Index (CPI) for Canada, as [published by Statistics Canada](#), for the previous fiscal year. This change applies to all federal service fees. Fees will be increased by 2.0% as of April 1, 2020. The *New Substances Notification Regulations* require any person (individual or company) proposing to import or manufacture a substance that is new to Canada and meets the quantity threshold, to submit prescribed information to the Government of Canada. Below are links to the revised fee table, *New Substances Notification Regulations*, and the *Service Fees Act*.

[Revised Fee Table](#)

[New Substances Notification Regulations \(Chemicals and Polymers\)](#)

[Service Fees Act](#)

### Draft Screening Assessment for Sodium ortho-phenylphenate (SOPP)

The draft screening assessment for Sodium ortho-phenylphenate (SOPP) was published for a 60-day public comment period ending on April 29, 2020. The final screening assessment is anticipated to be released in February 2021. It is proposed that SOPP does not meet any of the criteria in CEPA. While exposure of the general population to this substance is not of concern at current levels, this substance is associated with human health effects of concern. Therefore, there may be concern for human health of exposure were to increase. Follow-up activities to track changes in exposure or commercial use patterns are under consideration. Cosmetics Alliance will not be submitting comments unless interest is shown by membership.

### Draft Screening Assessment for Benzoxazole (Fluorescent Brightener 367)

The draft screening assessment of Fluorescent brightener 367 was published for a 60-day public comment period ending on April 22, 2019. The final screening assessment is anticipated to be released in February 2021. It is proposed to conclude that fluorescent brightener 367 does not meet any of the criteria set out in CEPA. Cosmetics Alliance will not be submitting comments unless interest is shown by membership.

### **Post-Consumer Waste Update**

#### **Authority approves Residual Funds Addendum to MHSW Program Wind-Up Plan**

The Resource Productivity and Recovery Authority has approved Stewardship Ontario's (SO) Residual Funds Addendum to the Municipal Hazardous or Special Waste (MHSW) Program Wind-Up Plan.

The Residual Funds Addendum outlines the process of returning residual funds to stewards once the MHSW Program has ended and all financial obligations have been accounted for.

On December 20, 2019, the Authority received direction from the Minister of the Environment, Conservation and Parks clarifying how residual funds must be managed once the MHSW Program ends and all financial obligations have been accounted for. The Minister directed that residual funds should be returned to stewards in proportion to their contribution to the funds for each MHSW category.

SO submitted a draft proposal to the Authority in January 2020 and the Authority consulted on the proposal with municipalities, stewards and other affected stakeholders. Visit the Authority's [consultation webpage](#) to learn more about the consultation process and to read the consultation report summarizing the feedback received.

All other sections of SO's MHSW Wind-Up Plan were approved by the Authority in December 2019.

For details on the implementation of the MHSW Wind-Up Plan, visit [SO's website](#) or email [mhswwindup@stewardshipontario.ca](mailto:mhswwindup@stewardshipontario.ca).