Regulatory Essentials – July 3, 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 th 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** 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

Consultation on Potential Market for Cannabis Health Products

On June 19, 2019, Health Canada released a consultation on the potential market for cannabis health products that would not require a practitioner oversight. Health Canada is launching this consultation to seek feedback from industry on the kinds of products they would be interested in manufacturing or selling. Please take the time to review the consultation document. The

consultation closes on September 3, 2019. Cosmetics Alliance (CA) will be commenting on this consultation. We request stakeholders to send in your comments to CA directly to regulatory@cosmeticsalliance.ca

Consultation Document

NNHPD's Client Service Teleconference Call

The NNHPD Client Services teleconference will be held on Wednesday, July 3, 2019 from 2:00 to 2:30 p.m. The NNHPD will provide an update on the current state of Client Services in the Bureau of Licensing Services and Systems, the monograph revisions and new web-forms. The call-in details are below.

Toll-free number: 1-877-413-4781

Conference ID: 6789716

Management Changes at The Natural and Non-prescription Health Products Directorate

Dr. Martin Duplessis, Director of the Bureau of Product Review and Assessment has moved on to a new role in the Food Directorate as of June 24, 2019. Nana Bafi-Yeboa, Shiva Ghimire, and Virginie Treyvaud-Amiguet have graciously accepted to share the acting in the Director's position until Martin's replacement has been confirmed.

Dino Covone, Director of the Bureau of Consumer Health Products Modernization will also be moving on to a new role in the Food Directorate as of July 8, 2019. The NNHPD will be welcoming back Amanda Moir in this position effective on that date.

Finally, Dr. Bio Aikawa, who is currently A/Manager of the Stakeholder Engagement Division in the Bureau of Policy, Risk Management and Stakeholder Engagement (BPRMSE), will move to a new role as the Director General, Manon Bombardier's Senior Advisor starting July 2, 2019.

NNHPD's Spring-Summer 2019 Newsletter

On June 25, 2019, NNHPD released its Spring-Summer 2019 Newsletter that highlights the accomplishments made since the last newsletter in December 2018. Accomplishments include Natural Health Product Applications Policy, Self-Care Framework, Plain Language Labelling for Non-prescription Drugs, Cannabis, Monographs, Client Services and more. Please take the time to review the newsletter.

Newsletter- EN

Newsletter - FR

Corrigendum to the Scientific Committee on Consumer Safety is Now Posted

A corrigendum to the SCCS opinion on salicylic acid has just been published here. Only the wording of the second point of the abstract page 3 was corrected (see highlighted text which has changed)**.** It clarifies that a substance which has been authorised up to a certain concentration (e.g. 0.5% as a preservative*)* can be used for other uses than preservative up to the same concentration. Unfortunately, the corrigendum also makes a shortcut from products that could lead to oral exposure to oral products wrongly placing lipsticks in the oral products

category (which is not considered with CPR where oral products and lipsticks are consider as separate categories).

2.In addition, does the SCCS still consider Salicylic acid (CAS 69-72-7) safe when used for purposes other than inhibiting the development of micro-organisms at a concentration up to 3.0 % for the cosmetic rinse-off hair products and up to 2.0 % for other products considering its current restrictions as reported above?

Based on the data provided and available literature, the SCCS considers salicylic acid (CAS 69-72-7) safe when used for purposes other than preservative at a concentration up to 3.0 % for the cosmetic rinse-off hair products and up to 2.0 % for other products, considering its current restrictions in place. However, in body lotion, eye shadow, mascara, eyeliner, lipstick and roll on deodorant applications, salicylic acid is considered safe up to 0.5 %. The SCCS position is that these levels are inclusive of any use of salicylic acid, i.e. should not exceed the stated levels with additional use as a preservative. This Opinion is not applicable to any oral product (such as toothpaste and mouthwash) with the exception of lipsticks. Sprayable products that could lead to exposure of the consumer's lung by inhalation are also excluded.

Health Canada Releases Regulatory Roadmap

Budget 2018 announced that the government would pursue a "regulatory reform agenda focused on supporting innovation and business investment. The goal is to make the Canadian regulatory system more agile, transparent and responsive, so that businesses across the country can explore and act on new opportunities, resulting in benefits for all Canadians."

This budget announced funding over three years for the Treasury Board of Canada Secretariat to coordinate targeted reviews of regulatory requirements and practices that are bottlenecks to economic growth and innovation. The first round of targeted regulatory reviews focused on three high-growth sectors:

- agri-food and aquaculture
- health and bio-sciences
- transportation and infrastructure

Health Canada released The Health and Biosciences Sector Regulatory Review Roadmap (https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-

guidelines/acts-regulations/targeted-regulatory-reviews/health-biosciences-sector-regulatory-review-roadmap.html) on June 7th which outlines their plan to address the issues, irritants, and bottlenecks identified by stakeholders that affect innovation and economic growth in the health and biosciences sector.

The initiatives in this roadmap aim to address issues raised across a variety of products, from cosmetics, natural health products, non-prescription drugs, and workplace chemicals to products that challenge traditional categories, such as software and 3D printers.

- A more integrated approach is needed to provide appropriate oversight and controls where products fall into distinct silos (cosmetics, non-prescription drugs, natural health products)
- Health Canada now operates in a global market with high volumes of imported products, making international regulatory cooperation and partnership imperative
- Greater focus on areas of highest risk for regulation and enforcement through a cyclical approach.
- Creation of more agile and dynamic systems to address today's product development environment, rapid innovation and new technologies to allow regulatory decisions in real time to bring products to the market more quickly.

The Regulatory Review process involved extensive stakeholder engagement, including the following:

- the Economic Strategy Tables;
- departmental consultations and bilateral discussions; and
- the Regulatory Review consultation in Canada Gazette, Part I.

as well as major associations and other stakeholder groups.

Health Canada took into consideration information it had received through other avenues, including ongoing engagement with stakeholders, and regulatory cooperation fora. This included the:

- Canada-United States Regulatory Cooperation Council (RCC)
- Canadian Free Trade Agreement's Regulatory Reconciliation and Cooperation Table (RCT)

- Canada-European Union Comprehensive Economic and Trade Agreement's Regulatory Cooperation Forum (RCF).

As such, Health Canada focussed its review on the following frameworks as addressed in their Forward Regulatory Plan 2019-2021 (https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan/plan.html)

- Canada Consumer Product Safety Act and its regulations
- Controlled Drugs and Substances Act and its regulations
- Food and Drugs Act and its
  - Food and Drug Regulations (as they relate to drugs only)
  - Medical Devices Regulations
  - Natural Health Products Regulations
- Hazardous Materials Information Review Act and its regulations

Of note are the following for our types of products:

Self-Care Framework

- more risk-based regulating
- providing consumers the information they need to make an informed choice
- measures to eliminate unnecessary duplicative requirements
- measures that will remove regulatory obstacles, reduce the overall cost of compliance, and support innovation in the cosmetic market

Health Canada's Novel Approaches

Re-testing requirements for imported lower risk drugs are duplicative and create administrative burden that outweigh the risk of the products

Risk-based Approaches

Limitations on the distribution of drug samples are causing barriers to access for Canadians.

Regulatory Modernization – Government of Canada Wants to Hear From You

The Government of Canada is pursuing a number of initiatives to modernize the Canadian regulatory system and improve its performance for both Canadians and businesses. To inform the direction of these initiatives, the Treasury Board of Canada Secretariat (TBS) is inviting input from all interested stakeholders on the following four initiatives related to its regulatory modernization agenda:

1. Targeted Regulatory Reviews (Round 2)
2. Review of the *Red Tape Reduction Act*
3. Legislating changes to regulator mandates
4. Suggestions for the next annual Regulatory Modernization Bill

A summary of each initiative, optional guiding questions, and instructions for submissions are available in the *Canada Gazette* Notice. Stakeholder submissions will be accepted until September 05, 2019. We look forward to receiving your input. Please use specific examples where applicable.

To provide your comments, please email your submission to RCD-DCMR@tbs-sct.gc.ca.

Environmental Updates

Survey on the Environmental Risk Assessment of Active Ingredients

Health Canada has been working with stakeholders to develop an approach for the environmental risk assessment of active ingredients in prescription and non-prescription drugs regulated under the Food and Drug Regulations (FDR). As a follow-up to the Fall 2018 survey and the consultations held this spring, Health Canada is seeking your participation in a survey to collect cost-benefit analysis data on a revised approach that reflects greater alignment with US FDA requirements and aims to reduce potential duplications and unnecessary burden. More specifically, we have removed the basic dataset at the Market Authorization stage and included a screening dataset in its place, which is expected to reduce costs incurred by industry. In addition, we have removed the volume triggers for importation and fabrication in favour of an annual reporting requirement as we understand that it is difficult to predict volumes for reporting.

Under this revised approach, industry would be required to submit data and information on the potential environmental toxicity of active ingredients, namely chemicals and polymers in both human and veterinary drugs, as well as organisms (living and non-living) in human drugs. Health Canada would use this data and information to conduct an environmental assessment of the active ingredients prior to their import, fabrication or sale. The intended outcome is to gather better suited environmental risk assessment data and information on active ingredients in drugs so that associated potential environmental or human health risks can be identified and mitigated.

A detailed explanation of the scope of substances captured, as well as the requirements for those substances is outlined in the overview documents included in this package. In addition to those documents, you may wish to refer to the current regulations which govern activities in this area:

1) New Substances Notification Regulations (Chemicals and Polymers): http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-247/index.html ; and

2) New Substances Notification Regulations (Organisms): http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-248/

The purpose of this survey is to understand how the revised approach would have an impact on your operational expenses, as well as the benefits that they may bring to your company/industry. Please note that there may be some questions that are not applicable to you. If this is the case, please respond "N/A". Respondents are asked to answer those questions that are relevant.

Your responses are important to Health Canada, as they will allow for a more accurate description of the potential costs and benefits of the revised approach. In preparing your responses, quantitative data is preferred. If quantitative data is not available, then please provide a brief description of the potential implications of the-revised approach, supplemented by qualitative information. You may also provide other costing considerations specific to your company/industry that may not have been specifically identified as part of the survey questions.

Health Canada welcomes your completed survey before the end of the summer.

Comments and completed surveys can be provided by email to: hc.lrm.consultations-mlr.sc@canada.ca

Or by mail to:

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[1] This includes active ingredients that are chemicals and polymers in both in human and veterinary drugs, as well as organisms (living and non-living) in human drugs.

Various Publications Under the Chemicals Management Plan

Alkyl and Imidazolines Group

The Draft Screening Assessment for the Alkyl and Imidazolines Group was published for a 60-day comment period ending on August 21, 2019. The list of the Alkyl Imidazonlines Group can be found here. As a result of this assessment, the Government is proposing that these 4

substances are not harmful to human health at current levels of exposure, and that they are not entering the environment at levels that are harmful to the environment. Cosmetics Alliance will be commenting based on memberships interest.

Resins and Rosins Group

The Draft Screening Assessment for the Resins and Rosins Group and the Risk Management Scope for CTO were published for a 60-day public comment period ending on August 21, 2019. As a result of this assessment, the Government is proposing that the substances in the Resins and Rosins Groups are not harmful to human health at current levels of exposure. Cosmetics Alliance will be commenting based on memberships interest.

The Government is proposing that tall oil, specifically CTO, is entering the environment at concentrations that may be harmful to the environment. It is also proposing that the other 11 substances are not harmful to the environment. Cosmetics Alliance will be commenting based on memberships interest.

Zinc and its Compounds

The Draft Screening Assessment for Zinc and its compounds and the Risk Management Scope for Zinc and Soluble Zinc Compounds were published for a 60-day public comment period ending on August 28, 2019. It is proposed to conclude that zinc and soluble zinc compounds meet one or more of the criteria set out in section 64 of CEPA. It is also proposed to conclude that zinc and soluble zinc compounds meet the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA. This is a positive note from a personal care perspective as the risk is not focused from an ecological or human health perspective. Cosmetics Alliance will be commenting based on membership's interest.

Chlorhexidine and Its Salts

The Final Screening Assessment for Chlorhexidine and its Salts and the Risk Management Approach was published. The list of Chlorhexidine and its salts can be found here. It is concluded that chlorhexidine and its salts meet the criteria under paragraph 64(a) of CEPA as they are entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. However, it is concluded that chlorhexidine and its salts do not meet the criteria under paragraph 64(b) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends.

On the basis of the information currently available on its potential to cause harm to human health, it is concluded that chlorhexidine and its salts do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is therefore concluded that chlorhexidine and its salts meet one or more of the criteria set out in section 64 of CEPA. It has also been determined that the chlorhexidine moiety meets the persistence criteria but not the bioaccumulation criteria as set out in the Persistence and Bioaccumulation Regulations of CEPA.

Volatile Organic Compounds (VOC)

Please note that the proposed Volatile Organic Compound (VOC) Concentration Limits for Certain Products Regulations were NOT published. This was a mistake. Please disregard the email from the Chemicals Management Plan (CMP).