Regulatory Essentials – January 20, 2021

Cosmetics Alliance Updates

Membership Renewal 2021

With 2021 fast approaching, we **need your involvement and commitment** with the renewal of your company's membership in order to help Cosmetics Alliance Canada advance the collective interests of the cosmetics and personal care products industry.

Steps to Renew

Advertising Cosmetics in Canada Presented by Ad Standards and hosted by Cosmetics Alliance

Date: Wednesday, February 10, 2021

Time: 2:00 pm - 3:30 pm EST

Cost: Member: $250 Non-Member: $395

Learn and Understand:

- Ad Standards' role in advertising self-regulation
- How to navigate the Guidelines for the Non-prescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims
- How to create compliant advertising messages

This session will include examples, a quiz and a Q&A session.

Training Certificates are issued for your records to each individual successfully completing the quiz.

Individual logins are required for each participant to obtain a training certificate.

Register

Pilot Certification Program with the Shark Water Foundation

Long time CA members Brian and Sandy Stewart of Tribute Entertainment continue the work of their late son, internationally acclaimed film-maker Rob Stewart of the Sharkwater Foundation who worked to raise awareness of the need to protect endangered shark species by ending the

use of shark-derived squalene in cosmetics. CA will be working with the Sharkwater Foundation in the new year to scope a pilot certification program to ensure cosmetic manufacturers are sourcing plant-based squalene from suppliers. CA members interested in participating can contact mdavis@cosmeticsalliance.ca.

Webinar - Ensuring compliance within the Cosmetics and Personal care industry post - COVID – 19

Date: Feb 18th
Time: 1:00 - 1:45 pm
Fee: Free for members

This webinar, presented by new member - SGS North America, will help to understand how remote auditing/ Certificate extension can help in maintaining certification during this time.

Objective

To share with audience information on how remote auditing/Certificate extension works to help them maintain certification.

To discuss how best to meet expectations of QMS when staff is working remotely and cover 3 - 4 of the most common obstacles facing the workforce in our Next Normal.

Agenda

- Remote Audits vs Certificate Extension
- Remote Workers and Maintaining Your Quality management system
- Common Obstacles to Overcome

Target Audience:

Quality Manager, Regulatory Managers, Compliance Managers, QA employees, Production Management

Register

Clarification Provided to Quebec Government to Ensure Objective & Consistent Determination of Cosmetics as “Essential” Related to Retail Shutdowns due to Pandemic

As previously reported, the Quebec government has left it to the discretion of retailers (and government officials/inspectors) to determine which cosmetics and personal care products are

included under the categories of “health” and/or “hygiene” for the designation of “essential” during the current restrictions on in-person retail sales. This has resulted in a subjective and inconsistent approach. Consequently, and with the encouragement of Quebec officials, CA issued Guidance to inform these decisions and to provide a more objective approach, which utilizes the statutory definitions of these products in the federal *Food & Drugs Act.*

Following concerns identified by some members, we plan to revise our guidance to provide greater clarity on the contribution to “health” and/or “hygiene” of products which are statutorily defined as “altering the complexion, skin, hair or teeth” (e.g. make-up, hair dyes, etc.).

As the Quebec government wished these determinations to be made by retailers, and have encouraged us as an industry association to provide guidance, we are seeking the Minister’s concurrence with our proposed approach and have provided additional information to support the recognition of products which “alter the complexion, skin, hair or teeth” as “health” and/or “hygiene” products and so considered “essential”.

Our letter to the Quebec Minister of Economy and Innovation, along with supporting materials can be found HERE. We will advise you when we receive the Minister's response and of any other developments.

Should you have any questions, feel free to contact Susan Nieuwhof.

Health Updates

HC Ends the New Exceptional Release for Importation Forms for Hand Sanitizers

As a reminder, back in March 2020, Health Canada introduced an interim measure for the exceptional release of hand sanitizers and surface disinfectants to expedite access to products that may not fully meet regulator requirements under the *Food and Drugs Act*.

This measure included Level 1 and Level 2 Self-Triage options.

Level 1 being the importation of a product authorized in Canada, but not fully compliant with requirements.

Level 2 being products not authorized in Canada but authorized or registered in the USA, an MRA country or a PIC/S country.

KEY POINTS:

- As of January 15th, Health Canada stopped accepting notification forms for hand sanitizers under this interim measure pathway. Health Canada has determined from

their market analysis that the supply of alcohol-based hand sanitizers now has sufficient domestic manufacturing capacity to meet demand.

- This change does not affect any products accepted into this interim measure and only applies to new applications. These currently accepted products will continue to be allowed to be imported and/or sold. For any applications that were made prior to January 15th and not yet accepted, will continue to be processed.
- This notice does not end the exceptional release of hard surface disinfectant products.
- If you have been accepted under this measure, Health Canada has indicated they will provide advance notice to companies, outlining the process when the interim measures expire.
- Health Canada is reverting back to the standard, pre-COVI-19 regulatory process for the manufacturing and importation of hand sanitizers located at relevant licences for these products and related establishments.

DEL Bulletin LEPP 104 Invitation Stakeholder information session on the allocation of drugs accessed via exceptional importation

On March 30, 2020, the Minister of Health signed the *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19*. The interim order (IO) allows certain drugs that may not fully meet regulatory requirements to be imported and sold in Canada. Further information on the IO can be found in the Explanatory Note.

As demand grew for certain critical drug products, a pattern emerged whereby companies were seeking direction from Health Canada and provinces and territories (PTs) on where to focus limited supply.

Through a new process, importing companies will receive direction from Health Canada and provinces and territories on how they can best serve the Canadian healthcare system by distributing alternative supply to where it's needed most. Furthermore, the process enables importing companies to identify jurisdictional willingness to commit to purchase alternative supply under a Purchase Order, prior to importation of product.

Health Canada will hold an information session for stakeholders on the allocation of drugs accessed via exceptional importation on Jan 25, 2021. To participate, please follow one of the following links:

English Session – Jan 25, 2021**, 01:00 PM** Eastern	**French Session -** Jan 25, 2021 **02:00 PM** Eastern
Join Zoom Meeting https://ca01web.zoom.us/j/69249691140 **Meeting ID:** 692 4969 1140 **Passcode:** 490366	**Join Zoom Meeting** https://ca01web.zoom.us/j/64287111156 **Meeting ID:** 642 8711 1156 **Passcode:** 556009

Upcoming NNHPD Webinars – NHP GMP and Compliance & Enforcement

The Natural and Non-prescription Health Products Directorate (NNHPD) and Regulatory, Operations and Enforcement Branch (ROEB) will be holding a series of webinars in January and February on NHP GMP and Compliance & Enforcement (C&E) respectively. Below is a summary of the webinars – please note each webinar has 2 English and 2 French sessions (they are the same webinars at different times). Invitations to the webinars have already been sent out and below are the supporting documentation for the webinars. If you have not received the invitation, please email regulatory@cosmeticsallianc.ca.

ROEB C& E Pre-read for C&E Webinar EN&FR QA C&E EN / FR	English Session 1: January 26, 2021 English Session 2: January 28, 2021 French Session 1: January 26, 2021 French Session 2: January 28, 2021
NHP GMP Licence Exploitation FAQ BPF Materiel Preparation Pre-reading Material Site Licence GMP FAQ	English Session 1: February 2, 2021 English Session 2: February 4, 2021 French Session 1: February 2, 2021 French Session 2: February 4, 2021

Notice to COVID-19 Site Licence Holders

The purpose of this questionnaire is to inform the Natural and Non-prescription Health Products Directorate (NNHPD) about the nature and intent of temporary COVID-19 site licence (SL) holders in order to strategically plan (e.g., resources, priorities) and determine the appropriate next steps for these temporary licensees, while ensuring a safe and sufficient supply of alcohol-based hand sanitizers remains available to Canadians.

Note: For COVID-19 site licence holders that elect **not to respond** to the questionnaire, it will be assumed that you **do not intend** to apply for a full site licence in order to continue to manufacture, package, label and/or import alcohol-based hand sanitizers after your current temporary COVID-19 site licence expires.

This questionnaire will be open until Friday, January 22, 2021. If you have any questions, please contact: hc.nnhpd.consultation-dpsnso.sc@canada.ca

The questionnaire can be accessed here:
https://ca1se.voxco.com/SE/?st=9O6sf%2B11A2MJEry3Z4DueoUnt21XtHP%2BAGQmSLujLPc%3D&lang=en

Regulations Amending the Food and Drug Regulations and the Medical Devices Regulations (Post-market Surveillance of Medical Devices)

On January 12, 2020 Health Canada amended the Food and Drug Regulations:

1 The portion of subsection C.01.014.6(3) of the *Food and Drug Regulations*[f] before paragraph (a) is replaced by the following:
(3) The Minister may cancel the assignment of a drug identification number for a drug if, after he or she has, under section 21.31 of the Act, ordered the holder of a therapeutic product authorization referred to in subparagraph C.01.052(1)(a)(i) or (iii) to conduct an assessment of the drug in order to provide evidence establishing that the benefits associated with the drug outweigh the risks of injury to health,

2 The portion of subsection C.01.050(2) of the French version of the Regulations before paragraph (a) is replaced by the following:

(2) Le titulaire d'une autorisation relative à un produit thérapeutique délivrée à l'égard d'une drogue appartenant à l'une des catégories mentionnées au paragraphe (4) fournit au ministre les renseignements dont il a reçu communication ou a connaissance concernant tout risque grave de préjudice à la santé humaine et se rapportant à la sécurité de la drogue en ce qui concerne :

3 (1) Subsection C.01.052(1) of the Regulations is replaced by the following:

C.01.052 (1) The Minister's power to make an order under section 21.31 of the Act in respect of a drug is subject to the following conditions:

- **(a)** the person to whom the order is made shall be the holder of one or more of the following therapeutic product authorizations in respect of the drug:
    - **(i)** a drug identification number that has been assigned under subsection C.01.014.2(1),
    - **(ii)** an establishment licence that has been issued under subsection C.01A.008(1), and
    - **(iii)** a notice of compliance that has been issued under section C.08.004 or C.08.004.01; and
- **(b)** the Minister shall have reasonable grounds to believe that
    - **(i)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(i) or (iii), the benefits or risks of injury to health associated with the drug are significantly different than they were when the authorization was issued,

- **(ii)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(ii) who is an importer, the manner in which one or more of the following activities is conducted may present a risk of injury to health associated with the drug:
    - **(A)** *importation*, as defined in subsection C.01A.001(1), of the drug,
    - **(B)** *fabrication* or *packaging/labelling*, as defined in subsection C.01A.001(1), of the drug outside Canada, or
    - **(C)** testing of the drug outside Canada, and
- **(iii)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(ii) who is not an importer, the manner in which an activity that is authorized under the authorization is conducted may present a risk of injury to health associated with the drug.

(2) The portion of subsection C.01.052(2) of the Regulations before paragraph (a) is replaced by the following:

(2) The Minister shall, after examining the results of an assessment that was ordered under section 21.31 of the Act in respect of a drug,

4 Section C.01.053 of the Regulations is replaced by the following:

C.01.053 The Minister's power to make an order under section 21.32 of the Act in respect of a drug is subject to the following conditions:

- **(a)** the person to whom the order is made shall be the holder of one or more of the following therapeutic product authorizations in respect of the drug:
    - **(i)** a drug identification number that has been assigned under subsection C.01.014.2(1),
    - **(ii)** an establishment licence that has been issued under subsection C.01A.008(1), and
    - **(iii)** a notice of compliance that has been issued under section C.08.004 or C.08.004.01;
- **(b)** the Minister shall have reasonable grounds to believe that
    - **(i)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(i) or (iii), there are significant uncertainties relating to the benefits or harms associated with the drug,
    - **(ii)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(ii) who is an importer, the manner in which one or more of the following activities is conducted has introduced significant uncertainties relating to the benefits or harms associated with the drug:
        - **(A)** *importation*, as defined in subsection C.01A.001(1), of the drug,

        - **(B)** *fabrication* or *packaging/labelling*, as defined in subsection C.01A.001(1), of the drug outside Canada, or
        - **(C)** testing of the drug outside Canada,
    - **(iii)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(ii) who is not an importer, the manner in which an activity that is authorized under the authorization is conducted has introduced significant uncertainties relating to the benefits or harms associated with the drug,
    - **(iv)** the holder of the therapeutic product authorization is unable to provide the Minister with information that is sufficient to manage those uncertainties, and
    - **(v)** the applicable requirements of these Regulations, together with any terms and conditions that have been imposed on the authorization, do not allow for sufficient information to be obtained to manage those uncertainties; and
- **(c)** the Minister shall take into account the following matters:
    - **(i)** whether the activities that the holder of the therapeutic product authorization will be ordered to undertake are feasible, and
    - **(ii)** whether there are less burdensome ways of obtaining additional information about the drug's effects on health or safety.

5 The portion of subsection C.08.006(3) of the Regulations before paragraph (a) is replaced by the following:

(3) The Minister may, by notice to a manufacturer, suspend for a definite or indefinite period a notice of compliance issued to that manufacturer in respect of a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission or a supplement to any of those submissions if, after the Minister has, under section 21.31 of the Act, ordered the holder of a therapeutic product authorization referred to in subparagraph C.01.052(1)(a)(iii) to conduct an assessment of the new drug in order to provide evidence establishing that the benefits associated with the drug outweigh the risks of injury to health,

Updated Interim Guide - DIN Hand Sanitizers and Disinfectants

Today, the Natural and Non-prescription Health Products Directorate (NNHPD) published the updated Interim guide on isopropyl alcohol for use in alcohol-based hand sanitizers and disinfectants.

Below are the key highlights of the updated Interim Guide:

- Interim order is still in effect – making small changes along the way
- Operation of pathway to bring Hand sanitizers and disinfectants from MRA and PCIS countries will continue as before but with the new Interim Order providing a more legal cover through Incorporation of Reference for disinfectants to provide additional certainty

- Will be moving away from the flexibility for DIN hand sanitizers to not provide a label mock-up
    - Sponsors are expected to provide label mock up within six months of the expiry of the current Interim order which is in March
        – no cost for this can be filed through the post DIN changes

Please take the time to review the updated Interim Guide and let us know if you have any questions or concerns.

Notification to Stakeholders: Changes to Senior Management Team

Recently, there has been an important change within the senior management team in the Natural and Non-prescription Health Products Directorate (NNHPD). Natalie Page will be the new Director General of NNHPD.

Natalie brings experience in strategic policy, engagement and planning in a regulatory organization.

Previously, Natalie was Vice-President of Public and Corporate Affairs of the National Capital Commission (NCC), where she was responsible for strategic communications, stakeholder engagement & Indigenous relations, marketing & partnerships and corporate planning for six years.

Cosmetics Alliance will be meeting with Natalie virtually to welcome her to her new role, brief her on our significant issues and how to move forward.

Environmental Updates

Publication of the second version of the Technical Guidelines for the Environmental Emergency Regulations, 2019

Environment and Climate Change Canada released today publication of the second version of the Technical Guidelines for the Environmental Emergency Regulations, 2019. This is an update of the December 2019 version. This guidance is for reference purposes and if you manufacture is Canada please take the time to review the updated Technical Guidance. To determine if you are impacted by the Environmental Emergency Regulations, 2019 please see Table 1 and Figure 1 in the Technical Guidance.

Various Publications Under the Chemicals Management Plan

Draft Screening Assessment of Decenes Group

The Draft Screening Assessment and Risk Management Scope for the Decenes Group was published on January 8, 2021 for a 60-day comment period ending on March 10, 2021. Unfortunately, it is proposed to be CEPA toxic however this conclusion was not directed by the cosmetic/personal care use applications but is generic CEPA Toxic designation. There are two substances in the group:

1. Hydrogenated didecene CASRN: 68649-11-6
2. Hydrogenated trimer and tetramer of decene (HTTD) CASRN: 68649-12-7

We will be engaging in the comment period only to indicate again the challenges we have with generic listing of substances as CEPA toxic when this is not driven by risk scenarios in the cosmetic/personal care space that were investigated and found not to present any risk. Unfortunately, the generic designation could have profound, unintended impacts that may implicate uses that were shown in the assessment to be safe (adequately protective) thereby stigmatizing legitimate uses. Please take the time to review the DSAR below and let us know if you have any comments or feedback. We will be circulating a draft copy of our comments prior to our final submission to the Chemicals Management Plan.

Decenes Group
The draft screening assessment and risk management scope for the Decenes Group was published for a 60-day public comment period ending on March 10, 2021.

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/decenes-group.html

The Final Screening Assessment of Acetic Acid

The Final Screening Assessment of Acetic Acid was released on January 15, 2021 by the Chemicals Management Plan. There are no changes from what was proposed to be concluded in the Draft Screening Assessment Report from July 2019. It is concluded that the substance does not meet any of the criteria set out in section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA). Since its is proposed to be 'non-CEPA toxic' no further action will be taken. Please take the time to review the final screening assessment and let us know if you have any questions or concerns.

Acetic Acid
https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/acetic-acid.html