Regulatory Essentials – August 14, 2019

Cosmetics Alliance Update

Cannabis Health Products Briefing

Cosmetics Alliance will be holding a Cannabis briefing regarding the recently published Consultation: Potential Market for Cannabis Health Products on Tuesday, August 27, 2019 from 1 p.m. to 4 p.m. The briefing will take place at Kao Canada Inc. The purpose of this meeting is to bring members up to date on current regulations for Cannabis products as well as have an open dialogue on the recently published consultation.

Learn About:

The difference between hemp and cannabis
The nuances of Canadian Market and U.S. Market
The distinction between Cannabis recreational products and proposed Cannabis Health Products
Differences between Cosmetics containing Cannabis and Cannabis Health Products
Location:

Kao Canada Inc.

75 Courtneypark Drive West, Unit 2

Mississauga, ON

L5W 0E3

Date: August 27, 2019

Time: 1 p.m. to 4 p.m.

Join us for this CA complimentary event intended for businesses interested in bringing cannabis products to the Canadian market.

To register please email regulatory@cosmeticsalliance.ca

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

Reconsideration of Decisions Issued for Human Drug and Natural Health Product Submissions

The Natural and Non-Prescription Health Products Directorate would like to advise you that the Guidance Document: Reconsideration of Decisions Issued for Human Drug and Natural Health Products Submissions has been posted to the Health Canada website. When Health Canada issues certain negative decisions related to the submission review process for a human drug, including hard-surface disinfectants, or a natural health product, the applicant may request a reconsideration of the decision. This document provides Guidance regarding the process. This document replaces the guidance, "Reconsideration of Decisions Issued for Human Drug Submissions," issued 2015/04/01. This guide is for Applicants and Sponsors with submissions to Therapeutic Products Directorate, Biologics and Genetic Therapies Directorate, Natural and Non-prescription Health Products Directorate, as well as regulatory staff from these directorate.

Regulatory Modernization – Request for Stakeholder Comments

As a follow up form July 2, 2019, the Government of Canada is currently accepting submission to the Consultation on Regulatory Modernization, focused on four items:

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

With respect to the Regulatory Reviews, the government wants to highlight that, in August, the Government will hold webinars to share information on the second round of Targeted Regulatory Reviews. The second round of Reviews focuses on three areas: (1) Clean technology; (2) Digitalization and technology-neutral regulations; and (3) International standards.

Reminder from Health Canada – Regulation of Cannabis and its Derivatives

The *Cannabis Act* received Royal Assent on June 21, 2018 and came into force on October 17, 2018. Cannabis has been removed from the scope of the *Controlled Drugs and Substances Act* (CDSA) and is now subject to the *Cannabis Act* and its regulations.

Topical products containing these ingredients are not subject to the *Food and Drugs Act* if they meet the conditions of the *Cannabis Exemption (Food and Drugs Act) Regulations*. A licence under the *Cannabis Regulations* will be needed to manufacture all cannabis products – even if

they do not contain THC. This includes most products containing ingredients derived from industrial hemp, including cannabidiol (CBD), but excludes products containing ingredients derived from the grain of industrial hemp, provided they contain no more than 10 micrograms per gram (10 ppm) THC, as well as materials exempted from the definition of cannabis under Schedule 2 of the *Cannabis Act*. Please see the Cosmetic Ingredient Hotlist entries for "Cannabis, as defined in subsection 2(1) of the *Cannabis Act*" and "*Cannabis spp.* (hemp) derivatives" for further details on the conditions of use in cosmetics.

Those selling cosmetic products with Cannabis sativa seed derivatives that are exempt from the application of the *Cannabis Act* under the *Industrial Hemp Regulations* (IHR) should also be aware of the IHR requirements, particularly those set out in Section 2, regarding importation, exportation and wholesale sale of exempted derivatives or products made from those derivatives. The regulations can be found here:
https://laws-lois.justice.gc.ca/eng/regulations/SOR-2018-145/index.html

Until October 17, 2019, the only classes of cannabis that can be legally sold under the Cannabis Act are: dried cannabis, fresh cannabis, cannabis oil (including cannabis oil for topical use), cannabis plants, and cannabis seeds. These products can only legally be sold by provincially- or territorially-authorized cannabis retailers or by a federally-licensed seller of cannabis for medical purposes.

Health Canada has published new regulations for edible cannabis, cannabis extracts, and cannabis topicals. The Regulations will come into force on October 17, 2019. The regulations can be found here:
http://www.gazette.gc.ca/rp-pr/p2/2019/2019-06-26/html/sor-dors206-eng.html

You may find additional information on cannabis here:
https://www.canada.ca/en/services/health/campaigns/cannabis/industry.html

Should you have any questions regarding cannabis products, we encourage you to contact cannabis@canada.ca

You may also be interested in the Consultation on Potential Market for Cannabis Health Products that would not Require Practitioner Oversight, which is open for comment until September 3, 2019:
https://www.canada.ca/en/health-canada/programs/consultation-potential-market-cannabis.html

Cosmetics Alliance will be submitting comments and will be engaging with members soon. Stay tuned.

Release of the Revised Post-Notice of Compliance (NOC) Changes – Quality Guidance Document

Health Canada is pleased to announce the release of the revised Post-Notice of Compliance (NOC) Changes - Quality guidance document.

The Post-Notice of Compliance (NOC) Changes - Quality Guidance released in September 2009 provides a comprehensive guidance regarding the conditions for the categorization of any post authorization change and recommendations for supporting documentation.

The guidance has been revised to reflect the following changes:

Appendix 1

- Clarification of the conditions to be fulfilled and the reporting categories, for Supplements and Annual Notifications,
- Addition of changes that are considered Annual Notifications and changes to the supporting data for a Supplement and an Annual Notification,
- Change 16, Condition 1 modified to allow for changes in colour or flavour and addition of supporting information for the change.

Appendix 2

- Revisions made to the supporting data and clarification of one condition,
- Revisions to the French language version of the guidance document to better reflect the content of the English version of the guidance document.

For details, refer to the Document Change log in the guidance document.

Changes in thePost-Notice of Compliance (NOC) Changes - Quality Guidance are effective from the date of posting on the Health Canada website; all post-authorized Quality submissions should be reported as per the procedures detailed within.

Questions or concerns related to these guidance documents should be directed to:

Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
1600 Scott Street
Holland Cross, Tower B
2nd Floor, Address Locator 3102C1
Ottawa, Ontario
K1A 0K9

Facsimile: 613-941-1812
E-mail: hc.policy.bureau.enquiries.sc@canada.ca

Release of the Revised Notice Regarding the Post- Notice of Compliance Changes: Level III Form

1. Introduction

Revisions to change #2 (Appendix 1) have been made to the Guidance Document: Post-Notice of Compliance (NOC) Changes: Quality. The Level III changes form has been revised to reflect these changes.

Please note: Only the Level III changes form currently posted on the Health Canada website will be accepted.

2. When to file

A Post-Notice of Compliance (NOC) Changes (Level III) Changes form should be filed at the time the changes are implemented or annually during the Annual Drug Notification period depending on the type of drug (pharmaceutical or biologic) and the type of change made (Quality or Safety and Efficacy). Refer to Sections 2.1.3 and 2.2.4 of the Post-Notice of Compliance (NOC) Changes: Framework Document for more detailed information on when to file Quality or Safety & Efficacy Level III changes and what documentation should be submitted when filing these changes.

A Level III changes form should be filed for:

- New drugs that have received a Notice of Compliance (NOC) pursuant to section C.08.004 of the Food and Drug Regulations. These drugs may include pharmaceuticals, biologics, and radiopharmaceuticals for human use and pharmaceuticals, radiopharmaceuticals and certain biotechnological products for veterinary use.
- New drugs for which an NOC has been recommended but issuance of the NOC has been placed on hold.
- Drugs regulated under Part C, Division 1 of the Food and Drug Regulations that have received a drug identification number (DIN) pursuant to Section C.01.014.2 for Drug Identification Number applications – Biologic products (DIN-B).

A Level III changes form should not be provided for the following:

- Drugs regulated under Part C, Division 1 of the Food and Drug Regulations that have received a drug identification number (DIN) pursuant to Section C.01.014.2 for the following DIN types:
    - Drug Identification Number Application (DINA)
    - Disinfectant Drug Identification Number Application (DIND)
    - Category IV Monograph Drug Identification Number Application (DINF)
    - Veterinary Drug Identification Number Application (VDIN)

3. File Format and Content

Sponsors should complete a separate Level III changes form for each drug product and save them as separate PDF files.

A cover letter should not be provided in a regulatory transaction with a Level III changes form.

Supporting data should not be provided with the Level III changes form. If additional information is required, it will be requested. Any unsolicited supporting data will not be reviewed.

4. How to File

Health Canada strongly recommends that all Post-NOC Changes: Level III changes forms be filed in eCTD format via the Common Electronic Submission Gateway (CESG). Refer to the

Guidance Document: Preparation of Regulatory Activities in the Electronic Common Technical Document (eCTD) format for detailed instructions.

If not provided in eCTD format, the forms should be filed in “non-eCTD electronic-only” format. Refer to the Guidance Document: Preparation of Regulatory Activities in the “Non-eCTD Electronic-Only” format for detailed instructions.

Health Canada will not accept Level III changes forms provided in paper format.

Comments or questions should be directed to the Office of Submissions and Intellectual Property (OSIP):

Office of Submissions and Intellectual Property (OSIP)
Resource Management and Operations Directorate
Health Canada
Tunney’s Pasture, Finance Building #2
Address Locator: 0201A1
Ottawa, Ontario
K1A 0K9

Facsimile: 613-957-4140
Email: hc.ereview.sc@canada.ca

Release of the Revised Guidance Document: Post-Notice of Compliance Changes – Safety & Efficacy

Health Canada is pleased to announce the release of the revised Guidance Document: Post-Notice of Compliance (NOC) Changes - Safety and Efficacy.

The Guidance Document: Post-Notice of Compliance (NOC) Changes - Safety and Efficacy released in September 2009 provides a comprehensive guidance regarding the reporting categories for any post authorization change relating to safety and efficacy and recommendations for supporting documentation.

In June 2015, changes were made to reflect amendments to the Food and Drug Regulations: Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use) which came into force on June 13, 2015 for prescription products and those administered or obtained through a health professional.

In February 2016, changes were made to reflect that, under the Plain Language Labelling requirements, Level II and Level III changes no longer require the submission of mock-ups.

In February 2018, administrative changes were made such as:

- the rewording of sections to add clarity to existing text,
- the addition/deletion of examples,
- the addition of new terms to the Glossary, and
- clarification of when Level III changes should be filed and the documentation that should be submitted.

In addition, consequential changes have been made over the past several years to include new initiatives that have been implemented such as:

- The interim measure on how Health Canada initiated safety changes for human drugs under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) (2014) are managed.
- The Plain Language Labelling (PLL) Requirements for all non-prescription drugs that came into force on June 13, 2017. Specifically, the additional requirement of the Canadian Drug Facts Table (CDFT) on the outer label.
- As part of the Plain Language Labelling initiative, revisions to certain sections of the Guidance Document: Product Monograph resulted in changes to this guidance (e.g., Part III Consumer Information changed to Part III: Patient Medication Information and removal of the References section).

This version of the guidance reflects the following changes:

- The name of the Guidance Document for the Management of Drug Submissions is now the Guidance Document: The Management of Drug Submissions and Applications.
- For non-prescription drug products, the addition of two Level I - Supplement examples and the clarification of two Level III Changes.
- Examples of Level I - Supplements and Level III Changes, for prescription drugs have been deleted from this guidance and incorporated into the revised Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs. For non-prescription drugs, the examples for Level I - Supplements and Level III Changes - Annual Notifications remain in the guidance.

This guidance document becomes effective from the date of posting on the Health Canada website. Questions or concerns related to this guidance document should be directed to:

Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
1600 Scott Street
Holland Cross, Tower B
2nd Floor, Address Locator 3102C1
Ottawa, Ontario
K1A 0K9

Facsimile: 613-941-1812
E-mail: hc.policy.bureau.enquiries.sc@canada.ca

Environmental Updates

Second Webinar on Zero Plastic Waste by Environment and Climate Change Canada

Due to the significant interest in the first webinar on Zero Plastic Waste, Environment and Climate Change Canada (ECCC) is offering two additional one-hour webinars in English on August 21, 2019, to update partners and other interested parties on federal activities and next steps and to answer any key questions.

The webinars will provide an overview of the Government of Canada's commitments and actions as well as the ongoing work with provinces and territories through the Canadian Council of Ministers of the Environment.

Please click on one of the links below to register.

- August 21 from 12:00 – 1:00pm Eastern
- August 21 from 2:00 – 3:00pm Eastern

If you have any questions regarding the webinar, please do not hesitate to contact us at ec.plastiques-plastics.ec@canada.ca.

Notice of Intent to Vary or Rescind the Requirements under the Significant New Activity (SNAc) Provisions under CEPA to 110 Substances under CMP

This letter is to inform you of the publication on July 27, 2019 of a Notice of Intent to vary or rescind the requirements under the Significant New Activity (SNAc) provisions of *the Canadian Environmental Act, 1999* (CEPA) to 110 substances under the Government of Canada's Chemicals Management Plan, in the Canada Gazette, Part I. The names and CAS Registry Numbers of the 110 substances can be found in the Notice of Intent.

This Notice of Intent was developed following a January 2015 initiative by Environment and Climate Change Canada and Health Canada to review all SNAc Orders and Notices put in place from 2001 to 2014 that are still in force. The proposed changes to the SNAc requirements reflect the outcome of the review of SNAc Orders and Notices applied to 110 substances that were identified as High Hazard, Not in Commerce. Environment and Climate Change Canada and Health Canada have reviewed the current SNAc requirements for these substances to determine if they continue to pose a risk to the environment or human health, and to ensure that the application of the SNAc provisions are in accordance with current information, policies and approaches. Information on the review of SNAc Orders and Notices was published in January 2015 and is available here.

According to the information presented in the review of the SNAc requirements for these 110 substances, it was determined that 105 substances are considered to have environmental effects of concern. Therefore, it is proposed that they should remain subject to the SNAc provisions. Amendments to the SNAc definition of these substances will be made to ensure that the application of the SNAc provisions are in accordance with current information, policies and approaches.

Based on current information, it was determined that the other 5 substances are unlikely to meet persistence, bioaccumulation and inherent toxicity (PBiT) criteria and that they are unlikely to pose a risk to the environment. Therefore, it is proposed that the requirements under the SNAc provisions for these 5 substances be rescinded.

A significant new activity can include an activity that is not currently occurring or an existing activity involving a different quantity or occurring in different circumstances that could affect the exposure pattern of the substance. The SNAc provisions trigger an obligation for a person (individual or corporation) to provide, and for the government to assess, specific information

when a person proposes to use the substance in a significant new activity. The Minister of Environment and the Minister of Health assess the information provided by the notifier and other information available to them to determine whether the substance, if used for a significant new activity, could pose a risk to the environment or to human health and, if so, whether risk management is required.

Within 60 days of the publication of the Notice of Intent, any person may submit comments to the Minister of Environment with respect to the publication.

Comments can be submitted to the Minister of the Environment, using the online reporting system available through Environment and Climate Change Canada's Single Window, by mail to the Executive Director, Program Development and Engagement Division, Environment and Climate Change Canada, Gatineau, Quebec K1A 0H3, or by contacting the Substances Management Information Line.

Post-Consumer Waste Updates

Ontario's Special Advisor - Report on the Blue Box Program

The Minister of the Environment, Conservation and Parks (MECP) has received Special Advisor David Lindsay's report that outlines recommendations for transitioning the management of Ontario's Blue Box Program to producers of plastic and other packaging. The report offers ideas to improve recycling and increase the number of products that can be recycled, while ensuring the program continues to be accessible and convenient. Recommendations from the report will help inform the ministry's next steps in transitioning the Blue Box Program to producer responsibility. Some of the recommendations include:

- Transition should occur in a phased approach over six years;
- Regulations should make producers responsible for all printed paper and packaging they put into the market by setting clear goals for diversion from landfill;
- MECP should identify material-specific targets;
- There should be a common collection system comprising a standardized list of materials;
- During transition, scope should be limited to residential recycling with expansion to multi-family and public space taking place after the transition period ends. IC&I should also be outside the initial scope;
- MECP should consult and finalize new regulations that specify how the blue box will move to full producer responsibility; and
- Before the end of 2019, MECP should provide further direction to Stewardship Ontario outlining the timeline for transition.

Read the **full report**.

https://www.cosmeticsalliance.ca/ontarios-special-advisor-report-blue-box-program/