Regulatory Essentials – February 17, 2021

Cosmetics Alliance Update

Quebec Gov't Announces New Retail Rules for COVID-19 Closures

We are pleased to share that the Government of Quebec today issued the attached statement outlining various changes to retail sales covered by their COVID-19 closure order.

As of Monday, February 8, 2021, "non-essential retail businesses, including shopping centres and personal care businesses, will be able to resume their activities, while complying with the **restrictions on the number of customers admitted to commercial enterprises**. Shopping centres will have to ensure adequate supervision of common areas, to avoid any gatherings or loitering."

With this announcement, the question should no longer be relevant as to what cosmetics and other personal care products fit within the categories of "health" and/or "hygiene" products for the purposes of being considered "essential". All such products will be able to be sold within retails establishments as long as the retail facility, or facilities providing personal care services (i.e. salons, spas, etc.) comply with the restrictions on the number of customers on the premises at any given time.

Should your company encounter any issues as these new rules are put in place as of next Monday, please feel free to advise your CA team at snieuwhof@cosmeticsalliance.ca or 647-980-5161.

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 you understand how remote auditing and certificate extensions can help in maintaining your certifications during this time.

Objective

To share with attendees, information on how remote auditing and certificate extensions work to help them maintain certification.

To discuss how best to meet expectations of Quality Management System when staff is working remotely and will cover 3 of the most common obstacles facing the workforce moving forward.

Agenda

- Remote Audits vs Certificate Extension
- Remote Workers and Maintaining Your QMS
- Common Obstacles to Overcome

Target Audience:

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

Register

Health Update

DEL Annual Licence Renewals – Webinars

As a reminder to Drug Establishment Licence holders, your 2021 renewals are due on April 1st, 2021.

In case you missed Health Canada's annual licence renewal webinar series for Drug Establishment License renewals the Drug Establishment Licensing unit has shared the recordings from their 4 webinars on the topics of concern. The links are provided below. The content of the webinars covered the following topics:

- Completing the 2021 Annual Licence Review (ALR), ,
- Completing the Drug Identification Number (DIN) Annex,
- Completing the ALR Table A Annex,
- and how fees will be calculated.

Note - New for 2021:

Pause the clock policy – Implemented on April 1st, 2020 and applies to 2021 ALR the application, the clock will be paused.

Fees for 2021 ALR have changed with the coming into force of the *Fees in Respect of Drugs and Medical Devices Order* on April 1, 2020. Please refer to the *Fees for the Review of Human and Veterinary Drug Establishment Licence Applications* for detailed information. For fiscal year 2020-2021 DEL fees, please consult the Fee Table available on Health Canada's website

Human/ Human & Vet DEL - Fee Table

For questions, please contact the Cost Recovery Invoicing Unit at: hc.criu-ufrc.sc@canada.ca.

Webinar 1 ALR 101 – EN/ FR Recording

Webinar 2 DIN Annex Deck – EN/FR

Webinar 3 Table A Annex – EN/FR

Webinar 4 Fees Invoicing Deck – EN/FR

Transition Measures for Exceptional Importation Interim Order

Health Canada's held an information session on January 29, 2021, which discussed the Department's plan to remake the *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19* (the interim order).

Please find below a copy of the PowerPoint that was presented to stakeholders. The presentation explains proposed changes to the interim order, and also outlines Health Canada's plan to amend the *Food and Drug Regulations* and the *Medical Device Regulations* in fall 2021.

Details on the Proposal:

- 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 note this does not apply to NHP hand sanitizers.

Consultation Deck – Drugs FSDP Biocides EN/FR

Health Canada presentation for Nitrosamines Session Feb 10, 2021

Health Canada hosted a stakeholder information session on Nitrosamines in Pharmaceuticals on February 10, 2021. Please see below for the presentation deck.

Topics Covered:

- Challenges and Lessons Learned

- Proactive Measure and Risk Management
- Potential Root Causes and
- Considerations for API and DP Pharmaceutical Development
- Nitrosamine Risk in Biologics and Radiopharmaceuticals
- Update on Compliance and Enforcement Approaches
- Health Canada's Updated Question and Answer (Q&A) Document (updated 2020-12-15)

Next Steps:

- If your questions were not answered during the session, please email your question to hc.bps.enquiries.sc@canada.ca
- If you have any general feedback, please email hc.bps.enquiries.sc@canada.ca
- Health Canada will continue to share developments on Nitrosamines
- HC is going to continue to work with international partners to share information to continue to understand the root cause and presence of nitrosamines in pharmaceuticals and to align efforts in the regulatory frameworks

HC Stakeholder Webinar

UPDATE - Regulations Amending the Food and Drug Regulations and the Medical Devices Regulations

The Food and Drug Regulations (FDR) and Medical Device Regulations (MDR) were amended on December 4th, 2020 with a coming into force date of 6 months after the Canada Gazette II posting for the changes to the FDR.

While the MDR changes are not in the scope of Cosmetics Alliance it is important that FDR regulatory amendments were included to clarify the regulations currently in place with respect to the assessment power and the authority to require tests and studies for drugs.

The amendments to the FDR were published to eliminate any potential inconsistencies or conflict in interpretation between the regulatory provisions for therapeutic products that are drugs and therapeutic products that are medical devices.

The proposed Regulations were pre-published in the *Canada Gazette,* Part I, on June 15, 2019, under their former title, *Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Post-market Surveillance of Medical Devices)*. The title has since been changed to *Regulations Amending the Food and Drug Regulations and the Medical Devices Regulations (Post-market Surveillance of Medical Devices)* to align with current drafting standards.

The Canada Gazette Part II posting is may be found here.

Environmental Update

Various Publications Under the Chemicals Management Plan

Dimethoxymethane

The Final Screening Assessment for Dimethoxymethane was published. It is concluded that Dimethoxymethane does not meet the criteria under section 64 of CEPA and is 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.

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

Protein Derivatives and Yeast Extract

The Draft Screening Assessment for Protein Derivatives and Yeast Extract was published for a 60-day public comment period ending on April 7, 2021. The DSAR proposes that yeast extract, protein hydrolyzates, collagen hydrolyzates and isostearoyl hydrolyzed collagen do not meet the criteria under 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. We will be submitting comments for the DSAR and will be working with out Risk Assessment & Ingredient Safety Committee.

CAS RN	Common name	DSL name
8013-01-2 [a]	Yeast extract	Yeast, ext.
9015-54-7 [a], [b]	n/a	Protein hydrolyzates
92113-31-0 [a], [b]	Collagen hydrolyzates	Collagens, hydrolyzates
111174-63-1 [a]	Isostearoyl hydrolyzed collagen	Protein hydrolyzates, leather, reaction products with isostearoyl chloride

https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan-3-substances/protein-derivatives-yeast-extract-group.html

Federal Environmental Quality Guidelines

A summary table of the Federal Environmental Quality Guidelines was published. Federal Environmental Quality Guidelines (FEQGs) are recommended chemical thresholds to support their federal initiative. FEQGs set a concentration so that if a given chemical is at or below the FEQG threshold, there is low likelihood of direct adverse effects from the chemical on aquatic life exposed via the water or sediment, or where chemicals may bioaccumulate, in wildlife (birds and mammals) that consume aquatic life. For more information regarding the recently published FEQGs please see below.

https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/federal-environmental-quality-guidelines.html

Post-Consumer Waste Update

Participate in the Authority's consultation on the distribution of Ontario Tire Stewardship surplus funds to stewards

The Authority is consulting on Ontario Tire Stewardship's (OTS) plan to return remaining Used Tires Program surplus funds to stewards. The plan was developed by Grant Thornton Limited, the court appointed OTS liquidator, as a Surplus Funds Addendum to the Used Tires Program Wind-Up Plan. The Authority is hosting a webinar on Thursday, February 11, 10:00 to 11:30 a.m. to present the proposed addendum, answer questions and solicit feedback from stakeholders. Learn more and sign up for the webinar.

Proposed Hazardous and Special Products Regulation Posted for Feedback

The Government of Ontario is consulting on its proposed Hazardous and Special Products (HSP) Regulation under the *Resource Recovery and Circular Economy Act, 2016*. To view the draft regulation, visit the Environmental Registry of Ontario.

The new regulation will support the transition of the Municipal Hazardous or Special Waste (MHSW) program to a new system that makes producers environmentally accountable and financially responsible for their products at end-of-life.

The proposed HSP regulation outlines the following:

- Establishing a robust collection network where consumers can drop off their HSP for free
- Managing all collected materials properly, including meeting procedures for managing end-of-life products by recycling where possible, or proper disposal
- Providing promotion and education materials to increase consumer awareness
- Registering with the Resource Productivity and Recovery Authority
- Reporting, record keeping and other requirements to ensure an equitable compliance and enforcement framework

The government is seeking feedback on the proposed regulation from **February 11, 2021, to March 28, 2021**. To provide your feedback, visit the Environmental Registry of Ontario.

The government will be holding webinars to consult on the proposed regulation. If you are interested in participating, contact RRPB.Mail@ontario.ca.

The Authority will be the regulator mandated by the Government of Ontario to enforce the HSP regulation requirements when they take effect.

Other Update

Humber College – Seeking Industry Partnerships for new Health Sector Regulatory Compliance Graduate Certificate Program

Humber College is looking to build new partnerships with industry in the following fields to support their students in completing a 3-month internship to apply their knowledge and skills to real-world settings:

- Cosmetics
- Natural Health Products
- Pharmaceuticals / Biotechnology
- Cannabis
- Medical Devices
- Agriculture
- Food
- Government
- Private sector

For more information on the program and how to post for these paid and unpaid internship opportunities, please see the bulletins below.

HSRC – Future Employers and Students
HSRC – Graduate Certificate