Regulatory Essentials – December 9, 2020

Cosmetics Alliance Update

The Notorious Confusables - Interactive Training Session

Date: December 16, 2020

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

Cost: Member: $250 Non Member: $395

These often-confusing terms are used in the cosmetic, natural health product and drug industries.

- Where are you in this diagram?
- Are you who you think you are?
- Do you know where vendors fit?

These terms are very important when reading through the cosmetic, drug and NHP regulations and guidance documents.

Objectives:

- Become confident in differentiating these terms to ensure your compliance obligations are clear
- Learn what these terms mean and how to apply their definitions
- Compare and contrast the differences in these terms in each of the regulations

This interactive training session will teach you the differences and the importance of these terms to answer often-encountered questions and will include exercises, 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

Health Update

Health Canada's Risk-Based Compliance and Enforcement Approach for Plain Language Labelling of Marketed Non-prescription Drugs

Further to our previous Regulatory Essential communication on August 18, 2020 , HC has shared a Q&A document on the Regulatory Operations & Enforcement Branch Compliance & Enforcement approach for Plain Language Labelling (PLL) of Marketed Non-prescription Drugs.

This Health Canada announcement is aligned with our previous communication on this subject and this recent communication re-enforces this.

As a reminder, DIN holders are encouraged to continue to work directly with Health Canada with their Drug PLL compliance plans as they work toward full compliance for all products by the deadline. Please see below for the Letter to OTC DIN Holders from Robin Churchill and Linsey Hollett and the corresponding PLL Q&A document.

Letter to OTC DIN Holders – EN/FR

HC Q&A: PLL for NPD – EN/FR

Web PLA Version 4 and Sunscreen Monograph Update

The sunscreen monographs (primary and secondary) are now available for use in Version 4 of the web-based PLA. This means that compendial applications for these two product types are now validation-supported when completing Version 4 of the PLA and there is no need to use Version 3 for compendial applications for these products.

Other monographs that have been released and supported by Version 4 can be found at https://nnhpd-pla-dlmm-dpsnso.hc-sc.gc.ca/pla-dlmm/ as of December 5th.

Online Systems Issue – Here's who you should contact

If you are experiencing technical issues on any of Health Canada databases or online forms please contact the NHP Online Solution Team at hc.nhp.initiative-psn.sc@canada.ca (please do not contact Client Services). In the body of your email please answer the following questions below.

1. Brief of description what they were trying to do as they encountered the error.
2. What were they expecting vs what they received from the forms/websites.
3. A snapshot of errors/error messages.
4. When did they first encounter this issue (time/date) and is it repeatable (on the same and/or different computer) or intermittent?
5. Anyone else in their organization encountering the same issue or is it localized to their computer alone?
6. The browser and operating system (windows vs mac) that they are using.

7. Is there an existing ticket/is this a follow-up? Did they notify anyone else or is this the first complaint?

Drug Submission Performance Quarterly Reports (January-September 2020): TPD, BRDD & NNHPD

The publication of the Quarterly Drug Submission Performance Report was cancelled for two quarters (there were no reports published for Q4 Jan-Mar 2020 and Q1 Apr-Jun 2020), however figures for the past three quarters are provided in this report.

Please find below the TPD, BRDD & NNHPD Drug Submission Performance Quarterly Reports (January-September 2020).

TPD – EN/FR

BRDD – EN/FR

NNHPD – EN/FR

NNHPD Site Licence Renewals

NNHPD is providing an update on the status of site licences, based on different scenarios, to ensure transparency and clarity for all site licence stakeholders.

1. For applicants that submitted their renewal application and received an updated site license:
    - You may continue operations. Your updated expiry date can be found on the new site licence.
    - Your next renewal application must be received, per the NHPR, at least 30 days prior to your new expiry date. You must use the new Web SLA form.

2. For applicants that have submitted their renewal application, but have yet to receive a decision:
    - As long as you have received an acknowledgment from NNHPD confirming that your renewal application has been received, you may continue your operations. In addition, you will continue to be listed as a licence holder until a licensing decision is rendered.
    - If your application is complete, an updated Site licence will be issued and will be backdated starting from the last expiry date. Therefore, there will be no gap in the validity period between the old and new licences.

- You are requested to continue to monitor your email, including junk mail, to ensure that you respond to any information request notice, as a failure to respond could result in a refusal to renew your site licence.

3. For applicants that failed to submit their renewal application:
    - Your site licence has not been renewed and you can no longer carry out activities
    - You may submit a new application, including an SNC form and supporting evidence.

4. For applicants that submitted their renewal application, and were issued a notice of refusal:
    - Your site licence is no longer valid and you can no longer carry out activities.
    - You may submit a new application, using the new web-based site license application (SLA) form with a Summary of Net Change (SNC) form, supporting evidence and addressing the issues identified in the notice of refusal in the cover letter.

Reminders and updates for site licence holders

Reminder that with the launch of the Web SLA on November 12, 2020, that the flexibility period for submitting a site licence application using the pdf form ended November 30, 2020.

Moving forward:

- All site licence applications, including foreign site applications, must be submitted using the Web SLA available at: https://nnhpd-site-licence-dexploitation-dpsnso.hc-sc.gc.ca/websla/
- Paper applications will no longer be accepted.

- The Web SLA form includes a checklist guide for applicants, which should be carefully followed.
    - Incomplete applications will be refused.

- As a reminder, the NHPR requires that site licence renewals be submitted **no later than** 30 days prior to expiry. **Effectively immediately**, companies that do not submit an application to renew their site licence at least 30 days prior to expiry will be refused.

- The Site licence holders list will be updated in early December and reflect the site licences that are valid as of December 1, 2020.

Information Session on DEL Bulletin No. 100 – New Interim Order – Safeguarding the Drug Supply

An Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply) was published and became effective on November 27, 2020.

Natural health products and over the counter drug products are **excluded** from this Interim Order.

Further information on this IO can be found in the Explanatory Note and a Guidance Document has been developed for products which are in scope.

If you are interested in attending this session, please follow one of the following links:

English Session – December 15, 2020**, 1:00 PM** Eastern	**French Session** December 15, 2020 **2:00 PM** Eastern
Join Zoom Meeting	**Join Zoom Meeting**
https://ca01web.zoom.us/j/64811968432	https://ca01web.zoom.us/j/66148804344
Meeting ID: 648 1196 8432	**Meeting ID:** 661 4880 4344
Passcode: 338033	**Passcode:** 739901

https://www.cosmeticsalliance.ca/information-session-on-del-bulletin-no-100-new-interim-order-safeguarding-the-drug-supply/

DEL Bulletin LEPP No. 101 Brexit: Summary information for Canadian companies

The United Kingdom (UK) withdrew from the European Union (EU) on January 31, 2020, and is now in a transition period, during which the UK and EU are negotiating future relationships. The transition period is set to end on December 31, 2020.

Recognizing the need for stability during the transition period, Canada has agreed that the UK can remain a party to the Comprehensive Economic and Trade Agreement (CETA) for the duration of the transition period.

As of January 1, 2021, CETA will no longer cover the UK; therefore, an interim Canada-United Kingdom Trade Continuity Agreement (Canada-UK TCA) will govern the terms of trade between Canada and the UK until a comprehensive free trade agreement is established. Canadian and UK Negotiators continue to finalize the agreement in preparation for signature and subsequent domestic approvals.

Once in force, the Canada-UK TCA will provide continued access to the benefits of CETA, on a bilateral basis, and Canadian firms will see little to no change in the terms of trade with the UK, post January 1, 2021.

Health Canada's Regulatory Operations and Enforcement Branch, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and the UK Veterinary Medicines Directorate (VMD) are discussing an interim arrangement for continued cooperation on the provisional application of the CETA Protocol on Pharmaceuticals, until the Canada-UK TCA officially enters into force, in an effort to avoid any trade disruptions. Specifically, this mean that Canada and the UK will continue to exchange Certificate of GMP Compliance and to accept batch certificate issued by a manufacturer without re-control of that batch at import.

Canada and the United Kingdom have long shared a profound and positive relationship, with a long history of working in partnership. The Government of Canada will continue to work closely with the United Kingdom to further enhance the bilateral trade relationship, including through a mutual commitment to negotiate a comprehensive free trade agreement that can be best tailored to the bilateral relationship and interests.

ROEB and the MHRA seek under this continuity agreement, to avoid any trade disruptions in the Protocols on Pharmaceuticals in that:

(1) Certificates of GMP Compliance will continue to be exchanged between the UK and Canada post-Jan 1, 2021

(2) The acceptance of Fabricator Batch Certificates between the UK and Canada will continue as evidence of batch compliance with GMPs for products transferred between the countries.

Health Canada's 2020 Virtual Stakeholder Meeting on Health Products

The purpose of this meeting was to help stakeholders better understand Health Canada's response to the COVID-19 pandemic and their plans for regulatory modernization.

A summary report of the meeting will be developed and shared in the coming weeks. In the meantime, you can access the presentation slides here.

Environmental Update

Various Publications under the Chemicals Management Plan

Final Screening Assessment of Phthalates:

The final screening assessment for the Phthalates Substance Grouping was published on December 5, 2020. It is concluded that fourteen substances do not meet any of the criteria set out in section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA).

Fourteen additional phthalates substances were also assessed within the scope of the assessment to determine the cumulative risk from combined exposure to phthalates. It is

concluded that DEHP may be posing harm to the environment and meets the criteria under section 64(a) of CEPA. A risk management approach has been published concurrently to outline the proposed risk management actions.

While exposure of the general population and the environment to 20 of the 28 substances is not of concern at current levels, these substances are associated with human health and/or ecological effects of concern. Therefore, there may be concern if exposure levels were to increase. Follow-up activities may involve including the substances in future information gathering initiatives, such as a mandatory survey under section 71 of CEPA.

- Final Screening Assessment
- Risk Management Approach
- *Canada Gazette* Notice

2019 Identification of Risk Assessment Priorities:

The results of the 2019 Identification of Risk Assessment Priorities Activities were published on December 4, 2020. The IRAP approach is a systematic compilation and review of information on substances from a large number of information sources. It enables the Government of Canada to communicate how emerging issues are tracked, and to identify and prioritize substances requiring further work.

The results of the 2019 IRAP review have been published and include recommendations for further scoping/problem formulation (85 substances), for additional data gathering (443 substances), and for monitoring of ongoing international activity (101 substances).

Results of the 2019 review

Publication of the Notice of intent to amend the Domestic Substances List

A Notice of Intent to amend the *Domestic Substances List* (DSL) of the *Canadian Environmental Protection Act, 1999* (CEPA), deleting 22 non-eligible living organisms, was published in the *Canada Gazette,* Part I, on December 5, 2020. A list of the confidential accession numbers of these substances can be found in the Notice of Intent.

After review, it was determined that the 22 living organisms listed in this notice do not meet the eligibility requirements set out in subsection 105(1) of the Act. Consequently, these living organisms are proposed for deletion from the DSL.

Stakeholders may submit comments within 60 days of publication of the Notice of Intent. Please provide any information on commercial activities that may be pertinent to this initiative. The final Order will be published in the *Canada Gazette*, Part II.

Comments will be taken into consideration during the development of the final Order, and stakeholders with current business interests in these living organisms (i.e. current importers or manufactures) will be engaged to facilitate a transition to the new reporting requirements and ensure continued compliance with the *New Substances Notification Regulations (Organisms)*.

Any person who manufactures or imports a living organism that they believe to be on the Notice of Intent may seek confirmation from the New Substances program by providing a Notice of *Bona Fide* manufacture or import of the living organism.

All comments must cite the *Canada Gazette*, Part I, and the date of publication of the notice. Comments can be submitted using the online reporting system available through Environment and Climate Change Canada's Single Window, by mail addressed to Thomas Kruidenier, Acting Executive Director, Program Development and Engagement Division, Environment and Climate Change Canada, Gatineau, Québec K1A 0H3, or by email to eccc.substances.eccc@canada.ca.

Post – Consumer Waste Update

Consultation on Stewardship Ontario's proposed Blue Box Program Wind-Up Plan ends

The Authority concluded its consultation on Stewardship Ontario's proposed Blue Box Program Wind-Up Plan on November 10, 2020. Extensive feedback was received during the consultation period and all comments will be considered when reviewing and approving the wind-up plan. Feedback will be summarized in a consultation report and posted to Stewardship Ontario' website following the approval of the plan. As outlined in the Minister's direction, the Authority is expected to approve the plan no later than December 31, 2020. Learn more.

Authority sets 2021 Blue Box Steward Obligation

The Authority has set the 2021 Blue Box Steward Funding Obligation at $152.1 million. The steward funding obligation is the total amount that stewards must pay to municipalities, First Nation communities and recycling associations for operating the Blue Box Program. In setting the 2021 steward funding obligation, the Authority used information obtained from the 2019 Datacall and applied the same methodology used to set the Final 2020 Blue Box Steward Funding Obligation. Learn more.

Other Update

ICCR Website Has a New Look!

The International Collaboration of Cosmetic Regulation a voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan and the United States who meet on an annual basis to discuss cosmetics safety and regulation, as well as enter into a constructive dialogue with relevant cosmetics industry trade associations. ICCR provides a multilateral framework to maintain and enable the highest level of global consumer protection by working towards and promoting regulatory convergence, while minimizing barriers to international trade. ICCR has recently updated its website with a new look which can be found here.