Regulatory Essentials – December 18, 2019

Cosmetics Alliance Updates

Membership Renewal

We need your involvement and commitment with the 2020 renewal of your company's membership in order to help Cosmetics Alliance advance the collective interests of the cosmetics and personal care products industry.

Renew Your Membership

Last Chance to Register for Cosmetic Labelling 101- Introduction to Cosmetic Labelling for Canada

December 19, 2019

2:00 - 3:30 pm plus1/2 h quiz

Designed for New Employees and New Cosmetics Alliance Members

Objectives

- Learn the language of cosmetics in Canada
- Overview of the Cosmetic Labelling Regulations
- Learn how other Canadian regulations apply to cosmetics
- Understand how these regulations interact with each other

Register

Only those electronically registered will be able to take the quiz and receive a training certificate. Limited spaces available!

Health Updates

NNHPD's Performance Against Service Standards

A previous communique was issued in June 2019 to inform site license stakeholders of delays in the review of site licensing applications. With the process improvement measures taken, NNHPD is on track to meeting its service standards.

In November 2019, NNHPD met the service standards for stream I, II, and III applications as follows:

Stream I: 35 business days, successfully met 94.1%;

Stream II: 65 business days, successfully met 90.6%; and

Stream III: 95 business days, successfully met 100%.

For further information on the applicable performance standards and application streams, please refer to the Site Licensing Guidance Document

Common Site Licence Application Deficiencies & Most Common Site Licence Enquiries

Since June 2019, the Client Services Unit has seen a decrease in the number of enquiries related to site licensing. NNHPD wishes to continue to provide feedback on improving site licence applications and build on previous recommendations.

NNHPD still receives several requests for a site license without the accompanying application form. In those instances, only a cover letter and some evidence are submitted. These requests cannot be processed for obvious reasons. To apply for a site licence, applicants must provide a site licence application form as per the Site Licensing Guidance Document. For a foreign site reference number (FSRN), applicants must complete a FSRN application form and include this form in the package sent to the NNHPD.

This notice serves as a reminder that an application form must be submitted for a site license request to be processed by the NNHPD. Not including an application form will result in a refusal.

NNHPD responds to a wide range of questions on good manufacturing practices and site licensing. In 2019, the most common site licensing questions related to the specific forms and documents that need to be submitted for a site licence application or foreign site reference number application.

The following list is intended to guide applicants, both new and existing clients, when preparing a site licence application (SLA), application to amend or renew a site licence, and/or a foreign site reference number (FSRN) application.

The forms and documents required as part of a SLA package are as follows:

1. Cover Letter (Recommended) – this document explains why you are sending in the application package;
2. Site Licence Application Form (Required) – this form gives all the necessary administrative information;
3. Designated Party Authorization (if required) – only required if someone other than the applicant is submitting the application;
4. Canadian Site (Required) – includes either a Quality Assurance Report, or Pre-Cleared Information;
5. Canadian Site Evidence (Required) – includes standard operating procedures, records, corrective and preventative actions;
6. Foreign Site (if required) – only required if the Canadian site is an importer, and may include a Quality Assurance Report, or Pre-Cleared Information, as applicable;
7. Foreign Site Evidence (if required) – only required if the Canadian site is an importer, and includes standard operating procedures, records, corrective and preventative actions;

The forms and documents required in a SLA renewal package or when re-applying for a site licence are:

1. Cover Letter (Recommended) – this document explains why you are sending in the application package;
2. Site Licence Application Form (Required) – this form gives all the necessary administrative information;
3. Designated Party Authorization (if required) – only required if someone other than the applicant is submitting the application;

4. Canadian Site (Required) – includes a Summary of Net Changes form, or Pre-Cleared Information;
5. Canadian Site Evidence (Required) – includes standard operating procedures, records, corrective and preventative action;
6. Foreign Site (if required) – only required if the Canadian site is an importer, and may include a Summary of Net Changes, or Pre-Cleared Information, as applicable;
7. Foreign Site Evidence (if required) – only required if the Canadian site is an importer, and includes standard operating procedures, records, corrective and preventative actions;

The forms and documents required in a FSRN application package are:

1. Cover Letter (Recommended) – this document explains why you are sending in the application package;
2. Foreign Site Reference Number Application Form (Required) – this form gives all the necessary administrative information;
3. Designated Party Authorization (if required) – only require if someone other than the applicant is submitting the application;
4. Foreign Site (Required) – includes either a Quality Assurance Report, Summary of Net Changes (for yearly updates and when reapplying for a FSRN), or Pre-Cleared Information;
5. Foreign Site Evidence (Required) – includes standard operating procedures, records, corrective and preventative actions;

For questions related to the submission process or site licensing requirements, please send an email to hc.nnhpd-dpsnso.sc@canada.ca. Any concerns or questions about this communique can be submitted to Stephanie Reid, Director, Bureau of Licensing Services and Systems at stephanie.reid@canada.ca.

NNHPD Client Services Teleconference Call Update

The Natural and Non-prescription Health Products Directorate (NNHPD) held a teleconference call on November 5, 2019 with industry associations. The purpose of this phone call is to provide an update o Client Services performance since the teleconference held on July 3, 2019. Additionally, Alysyn Smith spoke to the next phase in updating the suite of online tools to assist the license application process for natural health products.

Client Services:

- NNHPD has been receiving a high volume of status updates. NNHPD is striving to meet the service standard for product and site licence applications. Please note, NNHPD will not respond to status update inquiries if the application of interest is still within the performance standard. As such, NNHPD encourages you to hold status update requests within the performance standard.
- NNHPD has improved our response time; of the inquiries due in October 2019, approximately 70% received a response within the current 10-business day performance standard.

    - For inquiries that were more simple in nature (e.g., licence corrections, status updates, regulatory inquiries that did not require input from subject matter experts), approx. 80% of inquires were addressed within 10 business days.
    - For inquiries that required input from a subject matter expert (i.e., were more technical in nature), 60% were addressed within 10 business days.
        - Please note, as per the auto-reply, response time is expected to exceed the current service standard if consultation is required to address an inquiry.
- In comparison, one year ago, only 5% of inquiries were addressed within 10 business days.
- A contributor to this increase in performance is the fact that NNHPD completed the staffing actions to bring the client services unit to full complement.
- However, this state will be short lived and we will be going through a transition period, which will require us to backfill upcoming departures.
- Because the backfills may not fully line up with the departure dates, we have sought out interim measures to up the capacity in the unit. Despite these measures, we anticipate that our response time will slip below our October performance for November and December.

Ingredient support requests:

- An update on the current performance with respect to the review of requests to add or modify an ingredient within the NHPID was provided.
- As some of you already know, NNHPD have experienced a backlog in these reviews, stemming from a shortfall of staff this summer.
- The relevant teams within NNHPD have been assessing the situation in order to determine the best path forward and a realistic timing for when 'backlog' requests will be cleared.
- NNHPD is confident that, come December, any remaining reviews will be cleared.

System update:

- The Natural and Non-prescription Health Products Directorate (NNHPD) is entering the next phase in updating the suite of online tools to assist the license application process for natural health products.
- The next version of the web PLA that will validate class I submissions should be coming online in Winter 2020.
- To effect the migration to the new web form, the publication of new information in the Natural Health Products Ingredients Database (NHPID) was put on hold.
- During this interim period, the NHPID remained available as a reference document and requests to add a new medicinal or non-medicinal ingredient continued to be accepted and reviewed by the NNHPD.
- As of the week of December 2nd, NNHPD recommenced the publishing of data to the NHPID.
- Feedback regarding the web-based product license application can be provided to Alysyn Smith at Alysyn.smith@canada.ca.

Next Teleconference Call:

The next teleconference will be on Wednesday, January 22, 2020 at 2:00 – 2:30 pm. Call-in details will be sent to you closer to the date.

Quarterly Consumer Product and Cosmetic Report Summary Q1 2019-2020

The Consumer and Hazardous Products Safety Directorate regularly receives reports on human health or safety concerns related to consumer products and cosmetics. Industry is required to submit reports to the Consumer and Hazardous Products Safety Directorate when they become aware of an incident related to their consumer product. Percentage of reports received by product category:

Appliances: 22%; Housewares: 16%; Children's Products: 16%; Electronics: 11%; Home and Automobile Maintenance: 11%; Grooming Products and Accessories: 7%; Sports, Recreation, and Hobby: 7%; Outdoor Living: 7%; and Clothing, Textiles, and Accessories: 4%.

Note: Total does not always add up to 100 due to rounding.

Top 5 product types based on number of reports received

Electric Ranges or Ovens: 40; Cosmetics: 35; Power saws: 28; Riding power lawn mowers: 22; Swings or swing sets: 19.

Not every report the Consumer and Hazardous Products Safety Directorate receives involves an injury. Over this time period, injuries, including deaths, were reported in 36% of reports received.

218: Number of reports including an injury

Top 3 Injury Types

Irritations: 55; Cuts: 51; Burns: 30.

Natural and Non-prescription Health Products Directorate's Informatics System is Now Updated

The Natural and Non-prescription Health Products Directorate informatics system has been updated and the publication of new information in the Natural Health Products Ingredients Database (NHPID) started December 13th. Please see the NHPID what's new page for updates http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=whats.quoi&lang=eng. NNHPD presented this at our Fall Regulatory Workshop last week and we are pleased the new NHPID system is up and running. If you experience any difficulty with the NHPID going forward or think it is missing any ingredients or purposes that you have nominated, please let us know.

Updates to the Disinfectant Guidance Document

For those of you who are interested in disinfectants please see below the updates to the disinfectant guidance document. Below is the note from Health Canada.

Health Canada is consolidating the review of products currently dually-registered under two regulatory frameworks (the *Food and Drugs Act* and the *Pest Control Products Act*), under the *Food and Drugs Act,* for implementation in April 2020.

We are sending you this message in preparation for our December 17th, 2019 meeting, which is intended to provide updates concerning the transfer of dual-use, low-risk surface disinfectant - sanitizers, including updates to relevant guidance documents.

Prior to the implementation of this dual-use products transition, we would like you to review the attached documents and provide us with feedback within 45 days (January 30, 2020).

You may find the following list of key changes to be helpful for your review:

- Targeted changes required for the April, 2020 expansion of dual-use products to include soft surface sanitizers;
- Targeted changes related to harmonization with updated 2018 US EPA 810 efficacy guideline revisions;
- General changes to provide clarity on various data and label review considerations, in order to address common operational irritants and inefficiencies; and
- Targeted changes to introduce a request for a submission summary report to be included for disinfectant drug applications.
    - This request is on a voluntary basis to assist with providing context to what may otherwise appear as gaps/uncertainties within an application. The summary report will result in a reduction in clarification requests during the screening/review of the application. Similar requirement exists for other pest, drug and NHP applications and is considered an internationally accepted standard practice for industry.

Our goal is to provide you with the planned revisions to the guidance documents to allow for a smooth transfer. We note that we have used existing guidance documents online as a basis for the new draft documents. We will validate the translation entirely before publication. With this in mind, we would like you to only focus on the elements pertaining to dual-use, low-risk surface disinfectant-sanitizers.

GD1 English Clean

GD1 French Clean

GD2 English Clean

GD2 French Clean

GD3 English Clean

GD3 French Clean

Environmental Updates

Revised In Commerce List

The nomination process for the Revised In Commerce List (R-ICL) closed on November 3, 2019. Nomination packages received after November 3, 2019 will not be accepted. Manufacturers and importers who wish to market a new substance for use in *Food and Drugs Act* regulated products in Canada that is not already listed on the R-ICL or the Domestic Substances list must submit a notification under the *New Substances Notification Regulations* (NSNR) (Chemicals and Polymers) or NSNR (Organisms). Please take the time to review the list as this significant to our industry because tracking and reporting will be required if a new substance is introduced in a cosmetic/personal care product to substantiate their introduction under the NSNR.

Vulnerable Populations Consultation

A summary of feedback from the defining vulnerable populations consultation has been published. On November 22, 2018, Health Canada and Environment and Climate Change Canada launched a 60-day online consultation, inviting interested stakeholders and the general public to provide comments on the Government of Canada's proposed definition of vulnerable populations in the context of federal chemicals management activities. Though comments received from stakeholders offered a diverse range of perspectives, some consultation gaps were noted such as groups representing New Canadians. Additional efforts will seek to more

fully capture the views and concerns of others with regards to the proposed definition. CA will not be providing comments unless interest is shown by membership.

Draft Screening Assessment for Poly(alkoxylates/ethers)

The Draft Screening Assessment for the Poly(alkoxylates/ethers) Group was published for a 60-day public comment period ending on February 5, 2020. As a result of the draft screening assessment, the Government is proposing that the substances in the Poly(alkoxylates/ethers) Group are not harmful to human health at current levels of exposure, and that these substances are not entering the environment at levels that are harmful to the environment. As the DSAR indicates that Poly(alkoxylates/ethers) is not harmful CA will not be submitting comments. If you have any concerns on the DSAR and would like us to submit comments please email regulatoy@cosmeticsalliance.ca

European SCCS Draft Opinion on Zinc Pyrithione Posted

The European Union Scientific Committee on Consumer Safety (SCCS) has published a draft opinion on Zinc Pyrithione on their website for comment until February 24, 2020. This opinion was assessing safety of the ingredient regarding overall exposure from other sources. The report concludes that, “taking into account the scientific data provided, the SCCS considers Zinc Pyrithione (ZPT) as safe when used as an anti-dandruff in rinse-off hair products up to a maximum concentration of 1%.” This preliminary opinion adds to the SCCS opinions from 2014 and 2018 and to the overall weight of evidence on this ingredient’s safety profile.

The current Canadian Anti-Dandruff Products Monograph (updated in late 2018) allows for Pyrithione zinc to be used in rinse-off products at up to a 2% concentration. Cosmetics Alliance is not aware of any potential changes being planned for the Canadian Monograph at this time.