Regulatory Essentials – August 5, 2020

Cosmetics Alliance Updates

Cosmetics Alliance Interactive Training Series

How to Use the Web-Based Product Licence Amendment and Notification (PLAN) Form

Date: Wednesday, August 5, 2020

Time: 2:00 pm - 3:30 pm

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

Learn and Understand:

- What you need to do prior to submitting using the PLAN
- How to navigate and use the PLAN
- The resources available at Health Canada on using the PLAN
- How to submit the PLAN for gaining market access
- Where the PLAN is headed under the Self-Care Framework

Each session 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 Updates

Update on the AHA/PHA Cosmetic Ingredient Hotlist Entry

On July 14, CHPSD released a 'clarification Notice to Stakeholders (NtS) regarding their previous Notice regarding Considerations for the 2020/2021 Update to the Hotlist' as originally posted in January 2019. We initially believed that this would simply be a courtesy update acknowledging the delays in this process due to COVID activities, and that Health Canada was looking to provide a status update regarding their revise plans moving forward. This was certainly one of the purposes of this clarification notice as evidence by the information presented in blue at the top of the Notice. However, as previously reported, this update also provided some rather concerning clarifications regarding matters related to the alpha-hydorxy-acid (AHA) and polyhydroxy acid (PHA) elements of the Notice.

On Tuesday Cosmetics Alliance had a meeting with the CHPSD Team to clarify the intent of the updated Notice and to better understand and further elucidate how this fits within their updated hotlist process, specifically as this relates to their clarifications regarding AHAs and PHAs.

Based on the clarifications outlined by CHPSD, we understand that they believe that at this time, that they have sufficient science to affirm that, from their perspective, it is appropriate to infer that AHA's and PHAs are considered to be chemically equivalent with the same hazard profile to AHAs, and that by virtue of this conclusion, PHAs are captured in the current listing of AHAs in the Cosmetic Ingredient Hotlist.

Based on the work that CA Canada has been pursuing with our AHA/PHA Science Task Force (AHA/PHA STF) formed since the original NtS was posted in January 2020, we do not agree with this characterization of the available science, and we have been actively pursuing meetings with Health Canada to discuss the underlying science. As such, this clarification is inappropriate and premature and circumvents the established due process, as outlined below.

Why Members Need to be Concerned:

By issuing this clarification, CHPSD appears to be reverting back to their position as stipulated in May (at our 2019 Spring Regulatory Workshop), where it was suggested that the AHA entry on the current Hotlist should includes PHAs as opposed to allow for information and a review of science to inform them as to whether this is realistic, practical or scientifically supported. As such, this clarification appears to suggest that they have made up their mind and that their decision has been made, with no possibility to change their position, despite the fact that we have not been able to secure a meeting with them to discuss/review the science that we have been "gathering through our AHA/PHA STF. Correspondingly, this 'clarification' appears to step outside the established transparent and consultative process that we understood would be the path forward for Hotlist amendments in the future, which is highly unfortunate.

Recall that following our December Fall Regulatory Workshop, we were under the positive impression that CHPSD had heard the concerns expressed in our Spring Workshop and embarked in a process that would have them issue a Notice to Stakeholders (NtS) outlining their intent to consider changes or clarifications to the AHA entry to clarify how/if PHAs should be captured in this listing or if it is more appropriate to address PHAs in a different way. As outlined above, CA Canada has been gearing up for a follow-up scientific dialogue to inform these considerations/decisions with the hopes to enable clear differentiation between AHAs and PHAs given their unique profiles.

In issuing this 'clarification' it looks like CHPSD is taking a step backwards and subverting their established due process such that they wish to unilaterally proceed in a manner that is:

- Is retroactive
- Is Against their due process and
- Disregards the science input from stakeholders

We trust members would agree that this is unacceptable.

What We Are Doing:

In response to this lack of due process from CHPSD, CA has escalated this issue to the Office of the Director General (DG) of Healthy Environments and Consumer Safety (HECS) Branch. HECS has promised to reach out to CA by today after a debrief from the CHPSD team. CA hopes they will recognize the need for the appropriate due process, however if this is not the case CA will be escalating this to the Food and Drugs Liaison Office (FDALO), along with elevating our concerns at the level of the ADM and/or DM office.

What You Should Be Doing:

From our Fall Regulatory Workshop CHPSD notified us of an on-going Cyclic Enforcement Project (CEP) on AHAs to test the pH levels as outlined on the Hotlist and the AHA technical guidance. We recommend members to go over their product portfolio to determine which products contain PHAs or combination of AHAs and PHAs. As part of this ongoing CEP and the updated notice, an inspector may contact you over this matter and request to test products

containing AHAs or PHAs, remember you are within your rights to inquire and limit the scope implicated by what is on the Hotlist today, not what could be on the Hotlist tomorrow. Currently, the Hotlist does not represent PHAs under the AHA entry. For officials to insist otherwise would be inappropriate and we recommend that members reiterate such limitation in scope. It makes no sense to promote compliance on a matter which is still under consultation and being discussed for which only a notice of intent has been published. The whole point of the Hotlist amendment process that we have been negotiating over the past few years is to enable meaningful, active and practical consultation before action is undertaken and this being a prime example of where due process is not being followed. Currently, CA does not have a comprehensive list of PHAs however we have provided a list of PHAs that were highlighted at our workshop below.

List of PHA's:

- Gluconolactone
- Gluconic acid
- Lactobionic acid

CA's Next Steps:

- Awaiting response for the Director General of HECS
- Escalate to FDALO and ADM/DM office, if necessary
- Secure a science meeting with the Risk Assessment team at CHPSD

In the interim, please let us know if this activity hits your doorstep. Please take the time to review the updated Notice and do not hesitate to follow-up with your CA Regulatory Team if you have any questions or would like to discuss these developments further (regulatory@cosmeticsalliance.ca). This information should not be relied upon as legal advice in any way. Member companies are advised to consult with legal counsel to verify the applicability of any information provided.

Information Sharing - Status of ranitidine drugs in Canada

As you may recall, in September of 2019 Health Canada requested companies, to stop distributing ranitidine drugs in Canada as an interim, precautionary measure while the department assessed the risk of an impurity called N-nitrosodimethylamine (NDMA) detected in some drugs. Since then, companies have recalled certain ranitidine products from the Canadian market because they contained (or potentially contained) NDMA above acceptable levels.

In Canada, companies wishing to resume sale of ranitidine are required to meet testing requirements to demonstrate that products do not contain higher than acceptable levels of NDMA over their shelf life. Heath Canada continues to evaluate the issue and work with our international partners to identify potential causes and risk mitigation measures. As part of this evaluation, Health Canada has received information from our International Regulatory Partners regarding the observation of increasing levels of NDMA upon storage over time and at higher relative humidity and temperature conditions. In addition to stability concerns, there continues to be uncertainties surrounding the root cause(s) for the NDMA formation.

Based on its evaluation, Health Canada is allowing the continued availability of ranitidine products in Canada, provided companies undertake additional measures to provide added safeguards and address current information gaps.

As of July 21, 2020, Heath Canada requires companies wishing to sell ranitidine products in Canada to test each batch over its shelf life within shorter intervals and under different storage conditions, notifying Health Canada of test results on a routine basis and providing plans regarding studies of endogenous formation of ranitidine.

These additional requirements enable the Department to continue to monitor for NDMA in ranitidine products over their shelf life, and to take action as needed.

Health Canada will communicate publicly to inform Canadians of the status of ranitidine drugs in Canada once all MAHs have been informed. We will also share with you an embargoed version of the public communication once it becomes available.

If any further actions are planned by HC, or recalls are anticipated, we will proactively reach out to stakeholder associations.

Should you have any additional questions, please feel free to connect.

Ranitidine Update

Determination of the pH of Cosmetics and Similar Consumer Products using the PC-Titrate Instrument (C13.1)

On July 23, 2020 the Consumer Product Safety Program released the Determination of the pH of Cosmetics and Similar Consumer Products using the PC-Titrate Instrument (C13.1) Test method which was effective on April 4, 2020. Cosmetics Alliance is aware of the on-going Compliance & Enforcement activities regarding AHAs as previously communicated. Given the timing this is likely the method that Health Canada laboratory will be leveraging to support this activity. The method is not available on Health Canadas website. We have provided a courtesy copy below. We recommend to members whom have products containing AHA to review the method below in the event they are contacted by an inspector for product testing.

Members who do not have products containing AHAs please take note of this method to support any formulation that have pH controls for any future Compliance & Enforcement projects that may come down the pipe.

Please let your CA Regulatory Team know if you have any questions.

Test Method

Drug Submission Performance Annual Reports (Fiscal Year 2019-2020)

Please find below the TPD, BRDD and NNHPD Drug Submission Performance Annual Reports (Fiscal Year 2019-2020).

The Drug Submission Review Performance Reports provide detailed metrics about the timeliness of pre-market drug review process against performance service standards. The annual report compares five consecutive fiscal years (April 1 – March 31) from 2015-16 to 2019-

20. The reports are broken down by operational areas - The Therapeutic Product Directorate (TPD), Biologic and Radiopharmaceutical Drugs Directorate (BRDD) and Natural and Non-prescription Health Products Directorate (NNHPD).

TPD – EN FR

BRDD – EN FR

NNHPD – EN FR

Environmental Updates

Significant New Activities order for Phenacetin

The Order amending the *Domestic Substances List* (DSL) to apply the Significant New Activity (SNAc) provisions of the *Canadian Environmental Protection Act, 1999* (CEPA) to acetamide, N-(-4-ethoxyphenyl)- (also known as "phenacetin", CAS Registry No. 62-44-2), in the *Canada Gazette*, Part II was published on July 22, 2020.

The final screening assessment, published July 28, 2018, concluded that phenacetin does not meet any of the criteria set out in section 64 of CEPA.

However, since phenacetin may have human health effects of concern, there is a concern that new activities that have not been identified or assessed could lead to this substance meeting the criteria set out in section 64 of CEPA. Therefore, the Government has amended the DSL, under subsection 87(3) of CEPA, to indicate that the SNAc provisions under subsection 81(3) of that Act apply with respect to phenacetin.

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

Please take the time to review the Significant New Activity and let your CA Regulatory Team know if you have any questions or concerns.

Various Publications under the Chemicals Management Plan

The Final Screening Assessment for the Fatty Acids and Derivatives Group was published.

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

The Final Screening Assessment for the Nitro Musks Group was published.

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

The Final Screening Assessment for the Pigments and Dies Group was published.

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

All of the above-mentioned Final Screening Assessments do not meet any of the criteria set out in Section 64 of the Act.

Post-Consumer Waste Updates

Financial Update for Stewards Registered with Stewardship Ontario's MHSW Program

The Stewardship Ontario Board has reviewed finances in light of the recent Resource Productivity and Recovery Authority (RPRA) approval of the Industry Stewardship Organization (ISO) Surplus Fund Transfer Addendum and has set initial fee reduction schedules for some MHSW materials.

As Stewards are aware, there have been a number of important developments since the original wind up plan was developed. Importantly RPRA conditions associated with approval of the ISO surplus fund transfer changed the methodology by which the share of surplus funds to be allocated between Industry Stewardship Plan (ISP) Members and Stewardship Ontario Stewards is determined. In addition, the COVID crisis has increased financial risk for the organization as it makes plans to wind up the MHSW Program. The April Ministerial direction Stewardship Ontario received regarding the ISO surplus fund transfer also acknowledges the possibility of a potential extension of the MHSW Program or a delay in transition to MHSW operations under the *Resource Recovery and Circular Economy Act, 2016* (RRCEA). With 11 months remaining based on the current MHSW Program termination date, draft RRCEA regulations which are required to facilitate transition have not yet been published.

All of these developments require Stewardship Ontario to take a more cautious approach to the implementation of fee reductions than was originally anticipated in the MHSW Wind Up Plan submitted in September 2019. Stewardship Ontario does not wish to invoice stewards for wind up costs. As such it must retain certain reserve amounts to deal with potential cost increases associated with the MHSW wind up process.

Initial fee reduction schedules are highly dependent on program cost variables and will likely be adjusted throughout the wind up process. When it becomes clear that the MHSW Program will terminate as currently scheduled, Stewardship Ontario should be able to allocate additional amounts toward fee reduction at the end of the program.

The planned fee reduction process for various MHSW materials is described below. All schedules are subject to further review as the wind up process unfolds.

Pressurized Containers (Refillable and Non-refillable)

Stewardship Ontario will implement fee reductions for these materials beginning with invoices sent to Stewards at the end of July 2020. Stewardship Ontario has invited all pressurized container stewards to attend a fee reduction webinar on July 28, 2020 where it will provide an update of finances for the material category and outline its estimate of fee reduction amounts for the remainder of the wind up period and describe the invoicing process associated with implementation of fee reductions.

Single-use Batteries

The single-use battery program terminated on June 30, 2020. Stewardship Ontario will issue final invoices to stewards in this category at the end of September 2020. These invoices will include a fee reduction amount subject to final service provider claims and steward adjustment

reports and actual costs incurred in the material category. Stewardship Ontario will schedule an information webinar for these stewards at the end of September to provide an update of finances for the material category, identify the amount of the fee reduction associated with final steward invoices and describe the anticipated process for the eventual disbursement of any residual funds associated with the material category.