Regulatory Essentials - December 12, 2018

Cosmetics Alliance Update

2019 Membership Renewal

With 2019 fast approaching, we **need your involvement and commitment** with the **renewal of your company's membership** in order to help us advance the collective interests of our industry. Click here for the steps to renew.

Health Updates

Final Category IV Product Monographs Released

On December 7, 2018, NNHPD released the finalized Health Canada monographs for non-prescription drugs and natural health product license applications which have been revised to clearly delineate the products falling in category 1 as defined in the Self-Care Products Framework Proposal. The monographs are not on the NHPID and will be posted in the coming weeks. The updated monographs will be available in the new Web-based NHP PLA form upon the publication of the monographs on the NHPID.

Cosmetics Alliance will be reviewing the finalized monographs and welcome any comments/feedback you may have.

Anti-Septic Skin Cleansers – EN

Anti-Septic Skin Cleanser – FR

Medicated Skin Care – EN

Medicated Skin Care – FR

Athletes Foot – EN

Athletes Foot – FR

Diaper Rash – EN

Diaper Rash – FR

Oral Health Products – EN

Oral Health Products – FR

Throat Lozenges – EN

Throat Lozenges – FR

Primary Sunscreen – EN

Primary Sunscreen – FR

Secondary Sunscreen – EN

Secondary Sunscreen – FR

Acne – EN

Acne – FR

Anti-dandruff – EN

Anti-dandruff – FR

Health Canada's Compliance Verification Project – Wipes

EMERGING ISSUE

CA has been informed that some members have received requests from CPSD via RORB for compliance verification visits related to cosmetic wipes, including diaper/baby wipes. RORB is making visits to obtain samples as part of their routine compliance program.

WHAT MEMBERS NEED TO KNOW

After speaking to the Risk Management Bureau, we have ascertained that as part of this verification, Health Canada will be testing for microbial contamination and have referenced ISO standards. This is in line with compliance with the Section 16 general prohibition regarding unsafe products. While ISO has always been referenced as a guidance for Canadian companies to use to facilitate compliance, it is not an absolute requirement. We understand that not all companies use ISO standards or guidelines in their safety testing protocols. We want to notify members that HC may reference ISO so that you can prepare for any potential visits your company may have.

POTENTIAL BUSINESS IMPLICATIONS

If Health Canada tests your wipes and finds a different microbial result from your own testing, they can request a recall/stop sale of your product.

RECOMMENDATIONS – WHAT MEMBERS SHOULD DO

In the event of any positive test findings are microbials, HC will likely follow up with companies. We recommend that if members are approached to provide samples, you should be prepared to do concurrent testing at your own or a third party facility in order to be in a position to counter any output from HC's analysis as well as to provide for a counter narrative, particularly if your company does not leverage ISO test methods.

Please notify your CA Regulatory Team if RORB approaches your company with a request for a visit. Do not hesitate to contact us should you have any questions.

Plain Language Labelling Compliance Plan

Health Canada would like to collaborate with associations and members for implementation of the Plain Language Labelling (PLL) Regulations for non-prescription drugs. To meet the retail compliance date of June 30, 2021 Health Canada would like to better predict the workflow. To improve the efficiency of product submission reviews, provide timely assistance to applicants in meeting the PLL requirements, and ensure that performance standards continue to be achieved by Health Canada to provide predictability to industry, Health Canada is reaching out and encouraging stakeholders to:

1. Share your workload and your PLL submission plans in a table format similar to the PLL Compliance Plan below. Also, it will be appreciated if you could clearly distinguish if submissions are for innovator, generic, private brand or cross-licensed product labels.

Communicate any challenges you are facing or anticipate facing during the health product lifecycle (manufacture, production, transport, logistic, packaging, etc.) as a result of complying with the PLL Regulations. For example, Health Canada would like to know if sponsors are required to increase package sizes and/or reconfigure package formats (e.g. adding additional panels or innovative labels), after exhaustion of all available flexibilities.

3. Warn Health Canada as soon as possible (at least 4 to 6 weeks in advance) when a high number of submissions or submissions including multiple SKUs will be submitted for review.

4. Proactively communicate any concerns or questions regarding drug submissions with Health Canada, particularly if uncertainties relate to multiple, similar product submissions.

Please find below the PLL Compliance Plan document that outlines the above mentioned. Cosmetics Alliance encourage members to fill out the Plan as this is an important opportunity to let NNHPD know the challenges with meeting the June 30, 2021 deadline. Please send in your plan to hc.nnhpd.consultation-dpsnso.sc@canada.ca.

PLL Compliance Plan

Health Canada Stakeholder Engagement Event

On June 27, 2018, Health Canada's Health Products and Food Branch (HPFB) welcomed health product stakeholders to an annual stakeholder engagement session. The objective of the annual event is to provide stakeholders with the opportunity to provide input on current priorities and initiatives. A consultation summary from the June 27th stakeholder engagement session is now available on Health Canada's website. Cosmetics Alliance encourages members to register for the Stakeholder Registry (CSIMS) to receive future notifications on health consultations.

CSIMS

Validation Rules for Regulatory transactions provided to HC in "non-eCTD electronic-only" Format

Health Canada is publishing a set of validation rules for regulatory activities in the "non-eCTD electronic-only" format. These rules build on the information provided in the Guidance Document: Preparation of Regulatory Activities in "Non-eCTD Electronic-Only"format and will assist sponsors in preparing their regulatory transactions for filing to Health Canada.

It is important for sponsors to ensure that the validation rules are followed accurately in order to avoid encountering validation errors. Although they may be updated in the future, Health Canada is currently validating regulatory transactions in "non-eCTD electronic-only" format using the rules listed in the table below. Stakeholders are encouraged to use a commercially available tool to validate their regulatory transactions in "non-eCTD electronic-only" format, prior to filing them to Health Canada.

Although the profile may be updated without further notice, as of March 30, 2019, Health Canada will be validating regulatory transactions in non-eCTD format using version 4.4 of the "non-eCTD electronic-only" validation rules.

Should you have any questions regarding the content of the notice, please contact hc.ereview.sc@canada.ca.

ID #	Rule Name	Rule Description	Severity
A – GENERAL			
A01	Empty Folders	This rule is configured to detect empty folders (folders without any files or subfolders) in the transaction structure. **TIP**: All empty folders must be deleted before submitting the transaction to Health Canada.	Error
A03a	File Size	This rule is configured to verify the size of the files. A warning will be generated for PDF files between 150 MB and 200 MB. A warning will be generated for other file types (excluding SAS XPT) between 100 MB and 200MB. **Revised** **TIP**: Check the size of each file before submitting to ensure it does not exceed the maximum limits.	Warning
A03b	File Size	This rule is configured to verify the size of the transaction. An error will be generated for PDF files greater than 200 MB, SAS XPT files greater than 1GB and other files greater than 200MB. **TIP**: Check the size of each file before submitting to ensure it does not exceed the maximum limits.	Error
A08	File types	This rule is configured to verify if the file extensions are valid. The acceptable file extensions are: .pdf, .doc, .docx, .xls, .xlsx, .wpd, .ppt, .pptx, .dat, .inf, .txt, .jpg, .png, .gif, .svg, .wav, .mp3, .mp4, .wmv, .jpeg, .tiff, .tif, .bmp, .sas, .xpt. **TIP**: • Ensure that the file types for your documents are accepted before submitting. • File extensions written in uppercase letters are not accepted. • Do not change the file extension manually.	Error
A09	Corrupt and password protected WORD documents	Word document will be reported as corrupted or password protected if one or more of the following situations occur: 1. Document is corrupt or unreadable 2. Document has password protection 3. Document has external DOTX references Note: This rule applies only to Word version 2007 or later (.docx). **New**	Error
B - PDF ANALYSIS			
B01	Corrupt or unreadable PDF documents	This rule is configured to detect corrupt or unreadable PDF files within the transaction. An Error will be generated if the document: 1. Cannot be opened because it is damaged or the encryption is too strong. 2. Appears to have zero number of pages. 3. Appears to be an application form, but the form content cannot be read. An example of situation number (3) could be a document appearing to have one page only and the page contains the text phrase “Please wait… If this message is not	Error

ID #	Rule Name	Rule Description	Severity
		eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document." **Revised**	
B24	PDF Protection	This rule is configured to detect if the PDF documents are password protected. An error will be generated if there is a password. **TIP**: Before submitting to Health Canada, ensure PDF documents are not password protected.	Error
B25	PDF version checking	This rule is configured to verify that if the PDF document versions are valid. The acceptable PDF versions are 1.4, 1.5, 1.6, and 1.7. **TIP:** Ensure the PDF documents are created using the acceptable PDF versions.	Warning
B32	PDF Protection: Owner password	Finds all documents with an owner password set, excluding forms regardless of their location in the folder structure. **Revised** **TIP**: Ensure that "No Security" is selected for the "Security Method" displayed in "File", "Properties" and then, "Security".	Warning
B36	Bookmarks - multi action	This rule is configured to detect all bookmarks with multiple actions assigned to them. **TIP**: Ensure that all bookmarks have only one action assigned to it. This action should open the destination page. These settings should be verified in the bookmark properties.	Error
B40	PDF documents with attachments are not allowed	This rule is configured to detect attachments and portfolio documents found in PDF documents. **TIP**: Ensure that the PDF document does not include attachments or portfolio documents.	Error
B44	PDF documents with more than 10 pages must have bookmarks	This rule is configured to verify if PDF documents greater than 10 pages have bookmarks. Excluded from this check are: literature references in sections 3.3, 4.3, and 5.4; and Health Canada application e-forms.	Warning
B45	PDF Protection – Printing	Finds all documents where printing is not allowed. **New**	Error
B46	PDF Protection – Content Copying	Finds all documents where copying is not allowed. **New**	Error
B47	PDF Content restrictions	This rule checks for pdf files that contain JavaScript, dynamic content (e.g., audio, video or special effects), or 3D content. **New**	Error
C - REFERENCED FILES			
C05	Naming Syntax	This rule is configured to verify that the maximum path length including the first level folder of the regulatory transaction must not exceed 200 characters. The file names must not exceed a maximum of 64 characters, including the file extension. **Revised** **TIP**: File path length character count starts at the application folder and includes the file name.	Error
		I: Regulatory Enrolment Process* New ***ONLY for users of the Regulatory Enrolment Process (REP)**	

ID #	Rule Name	Rule Description	Severity
I01	Corrupt xml file	An XML file will be reported as corrupt if the file cannot be opened because the file is damaged.	Error

Environmental Updates

Draft Screening Assessment of Talc

On December 8, 2018, the Government of Canada (GoC) published their DRAFT Screening Assessment Report [DSAR] (and corresponding Risk Management Scope) for Talc [CASRN: 14807-96-6].

Despite our efforts in conjunction with the Industrial Minerals Association of North America (representing the talc producers) [IMA-NA] over the course of the past 4+ years, the GoC is proposing that talc be found 'CEPA-toxic' due to the following human health concerns:

- Potential inhalation risk due to exposures to "loose powders containing talc" leading to potential decreased lung function
- "Potential cause of ovaria cancer" associated with genital talc use

After reviewing these publications, Cosmetics Alliance has a number of scientific concerns regarding these conclusions and will be engaging in the consultation on this DRAFT assessment. As such, we are convening a special **SCIENCE TASK FORCE** to gather input and inform our commentary. This Task Force will support the efforts of our Risk Assessment and Ingredient Safety (RAIS) Committee as we coordinate our response and follow-up to these publications.

We are looking for safety science experts with expertise in the following areas:

- Inhalation toxicology
- Particle toxicology
- Carcinogenicity
- Epidemiology
- Reproductive toxicology/physiology

In addition, we may also need to access expertise on an ad hoc basis with:

- Raw material specialists (characterization of talc and talc specifications)
- Formulation experts (with knowledge of talc in formulation and particle characterization)

We will be reaching out to our supplier partners at IMA-NA to ensure their participation in this task force as well.

The **OBJECTIVES** of this Task Force are as follows:

- Complete a comprehensive review of the DSAR and critical studies driving the proposed conclusions

- Draft science support narrative that will form the basis of CA's RAIS formal response on the DSAR

Furthermore, members of this Task Force may be **CALLED UPON** for the following:

- Technical team to draw from as questions on our narrative/formal response arise
- Expert team to draw from as we look to engage on the science in the interim period between the close of the comment period and the finalization of the Screening Assessment

We will continue to work with RAIS on the developments related to Talc.

Draft Screening Assessment of Triarylmethanes Group

The draft Screening Assessment of Triarylmethanes Group and the Risk Management Scope Document for Basic Violet 3, Malachite Green, Basic Violet 4 and Basic Blue 7 were published for a 60-day comment period ending on February 6, 2018. As a result of the screening assessment the Government is proposing that Malachite Green may be harmful to human health at current levels of exposure. It is also proposed that the other 5 substances are not harmful to human health at current levels of exposure.

The Government is proposing that Basic Violet 3, Malachite Green, Basic Violet 4, and Basic Blue 7 are entering the environment at levels that may be harmful to the environment. It is also proposed that Pigment Blue 61 and Brilliant Blue FCF are not entering the environment at levels that are harmful to the environment.

The Government intends to add Basic Violet 3, Malachite Green, Basic Violet 4 and Basic Blue 7 to Schedule 1 of CEPA 1999, also called the List of Toxic Substances.

If the proposed conclusion is confirmed in the final screening assessment, the Government is proposing the following risk management actions to address human health concerns for Malachite Green:

- add Malachite Green to Health Canada's Cosmetic Ingredient Hotlist
- apply Significant New Activity provisions under CEPA 1999 to Malachite Green. The SNAc would require that the Government be notified of any proposed new activities related to Malachite Green, and that the new activity be assessed for potential risks to human health and/or the environment before being undertaken.
- further investigate the need for risk management of arts and crafts products containing Malachite Green, which may be used by children.

The Government is also proposing the following risk management actions to address ecological concerns for Basic Violet 3, Malachite Green, Basic Violet 4, and Basic Blue 7 (non-sulfonated triarylmethanes):

- work with stakeholders to further quantify sources of releases of non-sulfonated triarylmethanes to the environment throughout its lifecycle; and
- develop regulatory or non-regulatory initiatives that would limit releases of Basic Violet 3, Malachite Green, Basic Violet 4, and Basic Blue 7 from the pulp and paper sector to levels that would prevent or minimize the effects on the aquatic environment.

Toxic Reduction Program Announcement

The Ministry of the Environment, Conservation and Parks is proposing to make changes to reduce burden under the *Toxics Reduction Act, 2009* and Ontario Regulation 455/09.

The proposed amendments are intended to reduce burden associated with the overlap between Ontario's focus on toxic reduction planning and the federal government's Chemicals Management Plan requirements to take action on chemicals. By 2021, most substances regulated by Ontario's *Toxics Reduction Act, 2009* will be covered by the federal program. To avoid this unnecessary duplication, Ontario is proposing that facilities with existing toxics reduction plans will no longer be required to review their plans, and will refer to their existing plans for opportunities to reduce toxics. It is also proposed that any facilities entering the program will not have any planning, reviewing, or reporting obligations.

Only facilities with current plans for substances that meet reporting thresholds would continue to annually report on the amounts of those substances under the Toxics Reduction Program. Annual reports would continue to include information about the progress being made to reduce those substances.

This would preserve elements of the program that support Ontarians' right to know about toxic substances in their communities while maintaining the right balance between a healthy environment and a healthy economy.

The government is also proposing to repeal the *Toxics Reduction Act, 2009* and regulations made thereunder in 2021, and defer entirely to the federal government as they finalize their chemical management assessments and take action on substances deemed to be toxic.

The Ministry has posted the Act Proposal Notice and Regulation Proposal Notice on the Environmental Registry. Should you have any questions about this proposal you can call the Environmental Registry contact Michael Friesen at (416) 314-0131.

Mandatory Information Gathering for Certain Coal Tars and Their Distillates

The Government Published the Notice to provide information for the risk management of certain coal tars and their distillates on December 1, 2018 in CG1. The notice applies to six substances which are:

Substances

CAS RN footnote 1	**DSL name** footnote 2
8007-45-2	Tar, coal
65996-82-9	Tar oils, coal
65996-89-6	Tar, coal, high-temperature
65996-90-9	Tar, coal, low-temperature
65996-91-0	Distillates (coal tar), upper

Substances

CAS RN [footnote 1]	DSL name [footnote 2]
65996-93-2	Pitch, coal tar, high-temperature

Responses to this notice shall be submitted to the Minister of the Environment, using the online reporting system available through Environment and Climate Change Canada's Single Window. Inquiries concerning the notice may be directed to the Substances Management Information Line at 1-800-567-1999 (toll-free in Canada), 819-938-3232 (outside of Canada) or eccc.substances.eccc@canada.ca.

Government of Canada Releases the Draft 2019-2022 Federal Sustainable Development Strategy for Publication

The Minister of Environment and Climate Change, Catherine McKenna, released the draft 2019–2022 Federal Sustainable Development Strategy for public consultation and tabled the Government's 2018 Progress Report of the 2016–2019 Federal Sustainable Development Strategy.

The draft Strategy sets out the Government of Canada's environmental sustainability priorities, establishes goals and targets, and identifies actions that 42 departments and agencies across government will take to reduce greenhouse gas emissions from their operations and advance sustainable development across Canada.

The draft 2019–2022 Federal Sustainable Development Strategy demonstrates Canada's commitment to the United Nations' 2030 Agenda for Sustainable Development. It also recognizes the important role partners, stakeholders, and Canadians play in building a sustainable country.

The 2018 Progress Report shows how the Government of Canada is implementing the 2016–2019 Federal Sustainable Development Strategy, demonstrating that it is on track to meeting many of the commitments laid out in the Strategy. This includes highlighting the leadership role Canada has taken in working toward zero plastic waste and implementing measures to conserve marine areas, as well as actions on climate change.

For the next 120 days, stakeholders have the opportunity to provide comments on the draft Strategy. This feedback will help strengthen Canada's sustainability priorities.