

Regulatory Essentials – May 12, 2021

Cosmetics Alliance Updates

Virtual Spring Regulatory Workshop – Register Today!

Get ready for our first ever Virtual Regulatory Workshop on June 1st – 2nd, 2021. Cosmetic Alliance Regulatory Workshop provides members with the opportunity to stay up-to-date and informed on “everything regulatory”. Hear from government officials and Cosmetics Alliance staff on issues that will directly affect your business. Take part in our Member Engagement Session the next day to discuss what was heard the day before with your industry colleagues and CA Staff.

The regulatory workshop will also feature a new panel session with Health Canada’s Director Generals:

Linsey Hollett – HPCD (ROEB)

Roger Charland - CHPSD

Natalie Page - NNHPD

along with CAC’s President Darren Praznik.

This panel session will explore the future for the personal care product industry and how experiences over the last year can be leveraged in shaping the Self-Care Framework.

Do not miss out on this opportunity to engage with them and ask questions which matter to you.

Price of the workshop is per login; attendees can not share logins.

[Workshop Preliminary Agenda](#)

[Member Engagement Session Agenda](#)

Regulatory Workshop Details

Date: June 1, 2021

Time: 9:00 a.m. - 12:00 p.m. EDT

Location: Virtual

Cost: \$350 (including Member Engagement Session)

Member Engagement Session

Date: June 2, 2021

Time: 9:00 a.m. - 10:30 a.m. EDT

Location: Virtual

[Register](#)

Inspiring the Future – Spotlight Feature (For All Members)

Send us your videos!

At our upcoming Virtual Regulatory Workshop, CA Canada is looking to build an opportunity to bring a spotlight on member company stories that demonstrate our industry's perseverance through the dark times of COVID. Help us uplift the collective spirits of our industry as we strive to adapt to the new world that was and will be moving forward.

We Need Your Help! On Tuesday, June 1st we will be looking to spotlight our member companies in a new and exciting way. We are looking for videos that highlight positive reflections about your company, your people, and/or your products and services as our industry looks to recover from the challenging times of COVID.

We will be spotlighting these videos and other visuals during our Virtual Regulatory Workshop and in our inspirational montage that will also be displayed on our website and social media channels. All participating companies will be entered in a draw to win one of three free registrations to our Virtual Regulatory Workshop. This includes companies that have already sent us materials (including images) over the last few months.

[Signup Now](#)

Free Webinar -Today's Beauty Market and the Effects of COVID-19

NielsenIQ's Francis Parisien, Vice President, Eastern Canada, will share insights on COVID-19 impacts on the personal care products industry.

Date: Thursday, May 20, 2021

Time: 1:00 pm - 1:45 pm EDT

Cost: Member: Free Non-Member: \$50

What will be covered:

- Categories that have reached record-breaking sales as well as consumer data on on-line behaviors.
- How Canadians are rethinking beauty and changing their shopping patterns.
- The biggest trends and what's to come

[Register](#)

Interactive Training Session: INCI - What's in a Name

Date: Thursday, May 27, 2021

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

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

INCI nomenclature and the INCI registration process are important for stakeholders in the cosmetics industry to understand before selecting ingredients at the product development stage.

This interactive training session (which includes activities and a quiz) will help you learn and understand:

- o The history of INCI
- o The Canadian cosmetic ingredient labelling requirements (refresher)
- o The International perspective
 - Canada (CUSMA)
 - European Union Cosmetic Ingredient Database (CosIng)
- o How an INCI name is designated
 - Application process
 - INCI conventions
 - Publication
- o INCI name changes
 - Implications in China
- o wINCI and the InfoBase as resources

Presented by:

Joanne Nikitakis Sr. Director of Cosmetic Chemistry - Personal Care Products Council



Joanne Nikitakis is a member of the science team at the Personal Care Products Council as the Sr. Director of Cosmetic Chemistry. For more than 25 years, Joanne has been involved with the development of the INCI nomenclature program and publication of the International Cosmetic Ingredient Dictionary and Handbook in which she serves as principal editor. In her role, she serves as the staff liaison for the Council's Quality Assurance Committee and International Cosmetic Ingredient Nomenclature Committee, and provides technical support for activities associated with these Committees. Joanne has also served as editor of the Council's Quality Assurance Guidelines, and the Compendium of Cosmetic Ingredient Composition.

Ms. Nikitakis received her B.S. degree in Chemistry from the University of Mary Washington in Fredericksburg, Virginia, and M.S. in Pharmaceutical Sciences from the University of Cincinnati, College of Pharmacy in Cincinnati, Ohio.

Richard Parcels Assistant Director, Regulation & Market Access - Cosmetics Alliance Canada



Richard Parcels is the Assistant Director, Regulation & Market Access for Cosmetics Alliance Canada. He works to enhance and protect the ability of member companies to conduct business effectively in Canada by fostering industry and government cooperation and by using sound science and risk-based approaches to inform and shape regulation, policy and guidance.

Richard has over twenty years of experience in the pharmaceutical, natural health product, cosmetic and medical device fields. He obtained a B.Sc. in Microbiology from the University of Guelph and has previously worked at Agriculture Canada, Warner-Lambert Parke-Davis, AstraZeneca, Estee Lauder and as an industry consultant for 12 years. He specializes in regulatory affairs, quality systems, training and auditing.

[Register](#)

Health Updates

NNHPD Announcement – Amendment and Notification Form Version Update

The Natural and Non-prescription Health Products Directorate launched version 1.0.1 of the Amendment and Notification form.

This version is expected to improve the ability to triage amendments and notifications for review.

Please share your experiences with this new version with your CA Regulatory team at regulatory@cosmeticsalliance.ca.

Fixes within the Product changes section of the form include:

- Addition of a new field to identify whether or not the application is in response to a monograph revision.
- Revision of the term “Submitter” to “Application contact”,
- Revision to the list of salutations,
- Increase in character allowances for city, recommended use or purposes, directions for use, and risk statements,
- Improvements to the loading and display of product information for dosage forms, ingredient potencies, dosage ranges, and risk statements,
- Addition of the strain field for probiotics,
- Inclusion of the dosage unit field in the recommended dosage section,
- Correction to how the summary page represents changes to risk information, medicinal ingredient proper name and common name, directions for use, and non-medicinal ingredients,
- Revision to the list of application requirements to include the monograph attestation form (MAF) when attesting to a monograph,
- Removal of the ePLA (and its generated label) as an alternative to providing a revised label, i.e. only a revised label is required.

A company code is now a mandatory field in the Company updates section of the form and the Licence transfers section has been removed.

Any questions related to the amendment and notification form can be directed to Health Canada’s Client Services team via email (hc.nnhpd-dpsnso.sc@canada.ca). To facilitate triaging and timely responses at Health Canada’s end, please include a subject line that clearly indicates the inquiry is related to the amendment and notification form.

To report technical issues, please email [Natural Health Products Online Support](mailto:hc.nhp.initiative-psn.sc@canada.ca) at hc.nhp.initiative-psn.sc@canada.ca.

Web PLA Form Version Update 4.2.0

NNHPD released the version 4.2.0 of the web-based Natural Health Product Licence Application (web PLA) form on May 10, 2021. The new feature in this version enables the validation of 31 additional monographs.

Please share your experiences with this new version with your CA Regulatory team at regulatory@cosmeticsalliance.ca.

Below is a summary of features and fixes that are new to version 4.2.0:

- New recommended use or purpose feature allows user to add medicinal ingredients to traditional claims,
- Fixed medicinal ingredient source information save function,
- Fixed Quantity Crude Equivalent unit of measure save function when a range is provided,
- New restricted list of solvents by application class based on International Council for Harmonisation solvent classifications,
- New conditional field added to the risk information section when there is Iron in the product to support compliance with safety requirements when the package contains more than the equivalent of 250 mg of elemental iron. New feature in recommended dosage section allows user to identify specific recommended uses by subpopulation,
- General form style and formatting fixes,
- Fixed medicinal ingredient “additional quantity” form-level validation,
- Increased field length for medicinal ingredient quantity,
- Fixed frequency field validation (numerical characters only),
- Revised calculations table to include quantity fresh equivalent and quantity dry equivalent values,
- New dosage form-driven validation for non-medicinal ingredient requirements,
- New percentage conversions to enable dose and dosage calculations for validation,
- More specific validation error messaging.

Validation of the following 31 monographs have been enabled with version 4.2.0:

- Arnica
- Benzocaine
- Bilberry - Buccal
- Cayenne - Capsicum annuum - Topical
- Cod Liver Oil
- Cognitive function products
- Deglycyrrhizinated licorice - Buccal
- Deglycyrrhizinated licorice - Oral
- Devil's Claw
- Diaper Rash Products
- Elder - Sambucus
- Feverfew
- First aid antiseptics

- Goldenseal - Oral
- Grape Seed Extract
- Green Coffee Bean Extract
- Green Tea Extracts
- Holy Basil - Ocimum Tenuliflorum - Leaf
- Laxatives, Carbon Dioxide-Releasing
- Marshmallow - Althaea Officinalis - Leaf
- Marshmallow - Althaea officinalis - Root
- Medicated vapours
- Pancreatic Enzymes
- Poria - Wolfiporia extensa
- Propolis - Buccal
- Rhodiola - Rhodiola rosea
- Sage - Salvia officinalis - Oral
- Saw palmetto, liposterolic extract
- Serrapeptase
- Skullcap
- Whey products

The list of validation-supported monographs can be found on the [web PLA landing page](#). Applicants may begin using the web PLA form version 4.2.0 exclusively for all new product licence applications when attesting to validation-supported monographs.

The NNHPD will maintain access to version 3 of the form until all of its monographs can be populated and/or validated using version 4. For specific inquiries or to report technical issues or errors with the NHP Online System (e.g., web forms/databases), please email: hc.nhp.initiative-psn.sc@canada.ca.

Environmental Updates

Various Publications Under the Chemicals Management Plan

Confidentiality and transparency under the *Canadian Environmental Protection Act, 1999* (CEPA 1999)

Under section 313 of [CEPA 1999](#), any person who provides information to the Minister of Environment and Climate Change may request that this information be treated as confidential. This protects commercial interests by ensuring that confidential information is protected from public disclosure. The degree of protection given to such information is subject to sections 314-321 of CEPA 1999 and some provisions of the [Access to Information Act](#) (ATIA).

In October 2018, the Government of Canada updated and published the [Approach to disclose confidential information and promote transparency in chemicals management](#). This approach

seeks to balance transparency to support decisions in chemicals management with the right of stakeholders to protect confidential information.

In accordance with the approach, to help increase awareness of the substances in the Canadian market, confidentiality claims for substance identity will be reviewed after a period of 10 years. The Government of Canada has developed the [confidential substance identity claim review project](#), which implements a process to review these confidentiality claims.

The Government of Canada will review the confidentiality claims for substance identities in 4 phases: pilot phase, expanded scope, annual cyclical review and Government of Canada driven needs. The results of the Pilot Phase is now available.

Draft Screening Assessment and the Risk Management Scope for the Monocyclic and Bicyclic Sesquiterpenes Group

The draft Screening Assessment (DSAR) and the Risk Management (RM) Scope document for the Monocyclic and Bicyclic Sesquiterpenes Group was published on May 8, 2021 by the Chemicals Management Plan. Cosmetics Alliance will be reviewing the DSAR and RM scope and will be working on scientific commentary through its Risk Assessment & Ingredient Safety Committee. We will also be looking into setting up a Task Force with this committee to work on commentary as we anticipate extensive commentary to follow-up with like the Monoterpenes Grouping.

This will be discussed in detail at our upcoming committee meeting on May 12 at 2 p.m. EDT.

- [Draft Screening Assessment](#)
- [Risk Management Scope](#)
- [Canada Gazette Notice](#)

Chemicals Management Plan Science Committee

The meeting record for the February 2020 Chemicals Management Plan Science Committee meeting was published. A committee report on considerations for identifying potential risks from exposure to chemicals in the workplace was also published.

<https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/science-committee/meeting-records-reports.html>

Post-Consumer Waste Updates

Invitation: Biodegradable and compostable plastic packaging: GREENER on the other side

The Biodegradable and compostable plastic packaging: GREENER on the other side webinar, presented by Geneviève Dionne, Director, Ecodesign and circular economy along with Mario Patenaude, ecodesign and circular economy advisor at Éco Entreprises Québec and led by Philippe Cantin, Senior Director, Sustainability Innovation and Circular Economy at the Retail Council of Canada (RCC).

May 20, 2021 02:00 PM EDT

[Register](#)

Other Update

Internship Opportunity September – December: Humber College Seeking Industry Partnerships for the new Health Sector Regulatory Compliance Graduate Program

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

- 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 Employer and Students](#)