Regulatory Essentials – March 3, 2021

Cosmetics Alliance Update

Webinar - The State of Canada's Beauty Market and 2021 Outlook

Date: Thursday, March 25, 2021

Time: 2:00 pm - 2:45 pm EDT

Cost: Member: Free Non-Member: $50

The NPD Group's Alecsandra Hancas, Canadian Beauty Industry Analyst, will share our annual State of the Canadian Beauty Market insights. She'll also explore trends that shaped the Beauty Industry in 2020, including consumers' rising interest in skincare and "feel good" beauty. You'll hear insights on how Canada's lockdowns and work-from-home shift altered consumers' needs in 2020 and get Alecsandra's take on the trends we expect to continue in this year.

Register

Health Update

NNHPD Holds Virtual Stakeholder Meeting - Introduces New DG and Forward Regulatory Plan with Self-Care a Priority

CA participated in the Natural and Non-prescription Health Products Directorate (NNHPD) Multi-Association Meeting held virtually on January 29 during which NNHPD's new Director-General, Natalie Page, was formally introduced. The primary objective of the meeting was to review highlights of Health Canada's Forward Regulatory Plan 2020-2022.

The Forward Regulatory Plan provides information on regulatory initiatives that Health Canada aims to propose or finalize in the next 2 years through pre-publication in the Canada Gazette, Part I and final publication in the Canada Gazette, Part II. The Plan also includes regulatory initiatives that are planned to come forward over a longer time frame.

CA is happy to report that the Forward Regulatory Plan clearly establishes HC's post Covid-19 commitment to the Self-Care Framework as a priority. The Self-Care Framework will roll out in phases as follows:

- Phase I – Targeting spring 2021: Introduce, **for consultation**, targeted amendments to the Natural Health Products Regulations to improve labelling of natural health products (NHPs). This proposal will require essential risk information to be presented in a standardized format, with minimum font size and black-on-white contrast, making it easier to read, understand and compare with that for other similar self-care products,

such as non-prescription drugs, on store shelves. The use of plain language will also ensure that information on labels can be easily understood by Canadians. (These changes are necessary to eventually align labelling requirements for all cosmetic, natural health and drug products regulated together in each self-care risk category)

- Phase II – Targeting spring 2022: Targeted amendments to introduce **for consultation** a risk-based approach to regulatory oversight for non-prescription drugs. These include expedited pathways for lower-risk products. These changes are intended to align the oversight for non-prescription drugs with other self-care products of comparable level of risk. Regulations amending the Food and Drug Regulations, Part C (Agile Regulations for Licensing Drugs, including Self-Care Framework Phase 2 and the Use of Foreign Decisions)

- Phase III – Introduce **for consultation**, regulatory amendments to address evidence standards for similar health claims; extending risk-based regulatory oversight; and, seeking additional powers for Health Canada such as the ability to require a recall or label change for all self-care products.

IMPORTANT TO NOTE: Although there has been some delay in the Self-Care Framework due to Covid-19, your CA Team was successful in having some of the important benefits of Self-Care included in CUSMA (e.g. elimination of quarantine and re-testing provisions for imported products and relief from sampling provisions, for our types of products) which has now been in place since July 1st. It is estimated that this saves on average some $100K per year per SKU requested. We have also requested some additional interim relief measure that can administratively be put in place to further reduce unnecessary regulatory burdens while the formal implementation of the Framework is completed.

Advance Notice of Importation (ANI) Update

The evaluation by Health Canada of the Advance Notice of Importation Process pilot has now been completed. Based on the results of this evaluation, this process for cosmetics and drugs will no longer be considered a pilot and will continue as normal process.

The process to import non-compliant cosmetics and drugs for relabelling or modification to make their sale compliant in Canada remains as stated in the Advance notice of importation process for cosmetics and drugs, including the 3-month blanket period. However, as of April 1, 2021, the current Excel-based version of the Advanced Notice of Importation form will be replaced with a fillable PDF version. Although you may continue to use the current Excel-based form during this transition period, you can contact your Regional Health Canada office (linked below) to request a copy of the fillable PDF Advance Notice of Importation form for future ANI submissions.

ANI Update – EN/FR

Notification of updates to NNHPD Web Pages

The Natural and Non-prescription Directorate (NNHPD) has made recent updates to two of their existing webpages:

Health Canada has published a statement on the *List of disinfectants with evidence for use against COVID-19* webpage iindicating that the disinfectants on this list are expected to be effective against all strains of SARS-CoV-2, as genetic changes to the virus are unlikely to impact the efficacy of disinfectants.

Additionally, the *Applying for a Drug Identification Number (DIN) for a disinfectant drug during the COVID-19 pandemic* webpage has been updated to include expedited COVID review targets.

If you have any questions, please do not hesitate to contact us at regulatory@cosmeticsalliance.ca.

INCI Name Changes for Hydrocarbons

PCPC has recently made changes for the INCI name of hydrocarbons (isoparaffins and pareths). PCPC is also currently in the process of changing the platform for the INCI data bases, *wINCI and the InfoBase,* and anticipates publishing the amended names with the release of the new data base platform in early Spring. The new approach will replace the stem terms “isoparaffin” and “pareth” with “isoalkane” and “alketh” respectively, preceded by the appropriate carbon number designation. The rationale for the change is based on the alignment of INCI names with REACH, and specifically the approach taken by the Hydrocarbon Solvent Producers Association and the OECD Guidance for Characterizing Hydrocarbon Solvents which describes hydrocarbon substances by the carbon range and the term “alkane.”

Cosmetics Alliance suggests stakeholders to update their cosmetics notification form with the new INCI name of the above-mentioned hydrocarbons upon it release in Spring. Attached is the notice from PCPC regarding update on hydrocarbons.

Please take the time to review the update below and let us know if you have any questions or concerns.

INCI Name Changes for Hydrocarbons

Reminder: Regulatory Requirements – Alcohol Based Hand Sanitizer

On February 25, 2021 the Natural and Non-prescription Health Products Directorate (NNHPD) issued the compliance promotion notice (linked below) to all natural health product licence

holders who hold a licence for alcohol-based hand sanitizers. This notice also applies to technical grade ethanol hand sanitizers and hand sanitizers in beverage containers. This notice was sent out to stakeholders with the objective to promote awareness of the legal requirements for those making or selling natural health products and to support licence holders in meeting their regulatory obligations for licensed alcohol-based hand sanitizers.

Regulatory Requirements: Alcohol Based Hand Sanitizer – EN/FR

Section 22 and Section 12 Reminder for Product Licence Holders

Cosmetics Alliance (CA) would like to remind product licence holders of their obligations under Section 22 and Section 12 (2) (b) of the Natural Health Product Regulations to:

- Submit to Health Canada, prior to the sale of an NHP in Canada the following information, if it was not supplied at the time of application: and
- Submit (notify) to Health Canada within 60 days when the following information submitted to Health Canada has changed.

For each manufacturer, packager, labeller and importer:

- the person's name, address and telephone number, and if applicable, the person's facsimile number and electronic mail address, and if the person conducts the activity in Canada, the number assigned to the site licence issued in respect of that activity.

For each manufacturer, packager, and labeller:

- the address of each building where these activities occur

For each distributor:

- the name, address and telephone number, and if applicable, the facsimile number and electronic mail address

For each importer and distributor

- the address of each building in which the natural health product is stored for the purposes of importation or distribution

For each importer

- evidence demonstrating that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3.

This is important as these activities link the site names and addresses appearing on Site Licences with Product Licences.

Environmental Update

Government of Canada delivers on commitment to appoint an independent net-zero advisory body

The Minister of Environment and Climate Change, the Honourable Jonathan Wilkinson, launched the Net-Zero Advisory Body, an independent group of 14 experts from across the country, who will provide the Government of Canada with advice on the best pathways to achieving net-zero emissions by 2050. The Advisory Body is a key part of the proposed Canadian Net-Zero Emissions Accountability Act tabled in the House of Commons last fall, which would enshrine Canada's goal of net-zero emissions by 2050 into law.

Full Article

Cosmetics Europe Statement on ECHA RAC and SEAC Opinion on an Annex XV Dossier Proposing Restrictions on Intentionally added Microplastics

The *ECHA RAC and SEAC Opinion on an Annex XV dossier proposing restrictions on intentionally-added microplastics* published yesterday on the ECHA website, Cosmetics Europe posted online their statement. The statement can be accessed from the CE website homepage or directly via this link: https://cosmeticseurope.eu/echa-rac-and-seac-opinion.

The Proposed Restriction:

Shall not, from [entry into force (EiF)], be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w.

ECHA RAC's Opinion:

RAC considers that the proposed restriction on polymers as microplastics is the most appropriate Union-wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the scope and conditions are modified, as proposed by RAC.

SEAC's Opinion:

SEAC considers that the proposed restriction on intentionally added microplastics is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified, as proposed by SEAC, as demonstrated in the justification supporting this opinion.

Other Update

IFRA Information Letter 1107 on Clarifications Related to IFRA Standards

Please find linked below the IFRA Information Letter 1107 giving clarifications related to the implementation of IFRA Standards and categorization of product types in the 49th Amendment.

Clarifications Related to IFRA Standards