

## Regulatory Essentials – June 13, 2018

### Health Updates

#### PLL Lessons Learned Session Updates

The Plain Language Labelling (PLL) Lessons Learned Session took place on May 23, 2018. Health Canada provided associations with their next steps for drug PLL and their next steps with respect to the increasing complexities and conflicts between the Self-Care Framework and Improved NHP Labelling. [Part 1](#) outlines the history behind PLL and its current flexibilities. In addition, to the current flexibilities, there are two new flexibilities which are:

1. Acceptance of International Nomenclature of Cosmetic Ingredients (INCI) for Low Risk Products
2. Acceptance of Alternative Shapes

Also covered in this deck is their Proposed Interim Approach for Lowest-Risk Products (Category 1 under Self-Care).

[Part 2](#) of the PLL Lessons Learned Session introduced the Review and Analysis of Themes which was created from feedback Health Canada received from stakeholders including CA's PLL Case Study exercise with members who enrolled in this outreach opportunity. Each theme lists the challenges and considerations moving forward with further details/resolution which will be determined upon release of updated guidance documents on August 31, 2018 (refer to Slide 34). Below are the three themes, their challenges and considerations moving forward.

1. **Submission Management:** challenges with the administration of PLL, identified the need for increased predictability throughout the submission process and the challenges with mock-up submissions etc.
2. **Labelling Requirements:** challenges with expiry date format and alternative outer carton packaging such as foil and blister packages
3. **CDFT Flexibilities:** CDFT shapes limits useable space on container, active ingredients/purpose, headings, etc.

Cosmetics Alliance's input from our Committees and PLL Case Study Participants identified two key challenges to be addressed at the PLL Lessons Learned session which have been delivered upon:

- (1) The elimination of the duplicity (double label changes) between the SCF Phase 1 / NHP Improved Labelling initiatives. The SCF focuses on bringing NHPs in line with the principles and objectives PLL, through the implementation of [Facts Table Labelling \(FTL\)](#). Both these proposals currently excludes the large majority of "cosmetic-like" products. By proposing to implement this exemption for NHPs, while continuing to subject similar products classified as drugs in the interim, Health Canada would be furthering the divide that the SCF is ultimately looking to resolve.
- (2) Challenges with implementation of URLs on hosting sites

Other key asks from CA for drug PLL flexibilities, now **under consideration** by Health Canada, include:

- Use of an onsert
- Use of Category IV URL flexibilities in conjunction with innovative labels
- Alternative fonts exercise
- Clarity around recommendations and mandatory statements in GLPP Part 1
- Inadequate translations in CDFT Guidance Document and within the CDFT headings
- Expiry date formats
- Confusion between e-CDFT and standard CDFT among the various guidance documents
- Placement of URL on labels

#### Drug, PLL, NHP Improved Labelling and SCF Timeline

Further to the PLL Lesson Learned Session there are upcoming engagement sessions/milestones which are listed below:

- **Early July:** communication will be sent outlining the new flexibility for Category I self-care products and its associated implementation plan over the coming months.
- **Week of July 3<sup>rd</sup>:** revised CDFT and Question & Answer guidance documents will be emailed to associations for feedback. Associations will have two weeks to provide their written feedback.
- **Week of July 16<sup>th</sup>:** Stakeholders will submit their feedback on the CDFT Guidance document sent the week of July 3<sup>rd</sup>.
- **August 31<sup>st</sup>:** final revised CDFT, eCDFT, Question & Answer and the Good Label & Package Practices Guidance Documents will be released
- **October 2018:** in partnership with Regulatory Operations and Regions Branch (RORB) , a high-level outline of the post-2021 compliance and enforcement approach for the PLL requirements for non-prescription drugs will be shared.

#### Technical Session – Health Canada Webinar (e-CDFT/WET)

On June 26<sup>th</sup> from 10 a.m. to 12 p.m. the Resource Management and Operations Directorate (RMOD) team will be hosting a session by Webinar on the electronic Canadian Drugs Facts Table (CDFT). The purpose of this session is to review the current eCDFT implementation package and to discuss technical implementation perspectives and options. Health Canada may incorporate feedback from this session in updates to the Guidance document: Electronic Canadian Drug Facts Table Technical Standards and to the eCDFT templates by August 31. The intended audience for this webinar is **industry IT experts** who are responsible for implementing the eCDFT standards as the session will be examining the implementation package at the technical code level. To register for the webinar email: [hc.nnhpd.consultation-dpsnso.sc@canada.ca](mailto:hc.nnhpd.consultation-dpsnso.sc@canada.ca)

#### Risk Communication of Endocrine Disrupting Chemicals

On June 1, 2018 the [Science 2.0 – Join the Revolution](#) released an article on the Risk Communication About Endocrine Disrupting Chemicals (EDCs). The site states that several contemporary events scheduled for the European Union are bringing increased focus to the

topic of communicating risks about EDCs. This first took place on May 16 at the annual meeting of the European Chapter of the Society of Environmental Toxicology and Chemistry (SETAC) in Rome. A second discussion will be held at the annual; Helsinki Chemical Forum on June 14. The site states that EDCs do not pose a unique challenge for risk communication and that all environmental health threats pose the same set of challenges. Cosmetics Alliance believes that over communicating risks does not inform the reader and this is also in support of CA's work on Hazard Labelling and CEPA Review.

#### CIR Developments Bulletin

The one hundred forty-seventh meeting for CIR expert Panel took place on June 4 to 5, 2018. CIR developments are provided to any interested companies that manufacture personal care products or that provide raw materials, equipment or services for the industry. The CIR Developments Bulletin for this meeting can be found [here](#).

#### Environmental Updates

##### Federal Environmental Quality Guidelines for Bisphenol A, Hexavalent Chromium and Perfluoro Octane Sulfonate

The [Federal Environmental Quality Guidelines \(FEQGs\)](#) are recommendations in quantitative or qualitative terms to support federal environmental quality monitoring. FEQGs are set at a concentration so that where the concentration of a given chemical is at or below the FEQG, there is a likelihood of direct adverse effects. The Federal Environmental Quality Guidelines for Bisphenol A, Hexavalent Chromium and Perfluoro octane Sulfonate has been published. Cosmetics Alliance encourages stakeholders who are interested in these chemicals to review the FEQG and let your CA Regulatory Team know if you have any concerns.

#### Chemicals Management Plan Science Committee

Ensuring a strong science foundation is a key element of the [Chemicals Management Plan \(CMP\)](#). In support of this, Health Canada and Environment and Climate Change Canada, created a [CMP Science Committee](#) in 2013 to contribute expertise pertaining to scientific considerations in the delivery of the CMP.

This committee for the second 3-year term consists of 9 core members who will serve from summer 2017 to summer 2020. The first 3-year term of the CMP Science Committee ended in the fall of 2016. View the [meeting records and reports from the first term of the CMP Science Committee](#). Other related materials such as the lists of members and terms of reference for the first term are available upon request. Please contact: [hc.chemicalsubstances-chimiques.sc@canada.ca](mailto:hc.chemicalsubstances-chimiques.sc@canada.ca).

#### Post-Consumer Waste Updates

##### Reminder– Ontario's RPRA Authority, Annual General Meeting

The Ontario Resource Productivity and Recovery Authority (RPRA) will hold its Annual General Meeting taking place on Thursday, **June 21, 2018**, 9 a.m. to 12 p.m. at St. James Cathedral Centre (65 Church Street, Toronto, ON, M5C 2E9) **OR** via webcast. Further details including registration information are available on the Authority's [website](#).

Ontario's RPRA Authority – 2017 Annual Report is now available

Read about the wind up of the Used Tires Program, performance of four waste diversion programs, and other steps taken by RPRA to advance a circular economy, [here](#).

Save The Date – CSSA's 2018 Annual Steward Meeting

The Annual Steward Meeting of the Canadian Stewardship Services Alliance (CSSA) will take place on Wednesday, **October 24, 2018**. Held on behalf of its partner programs in Ontario, BC, Saskatchewan and Manitoba, this is CSSA's main event for keeping stewards informed about packaging and paper recycling programs and fee schedules. Details to follow at a later date. Additional updates from CSSA are available [here](#).

### International Updates

#### Taiwan's Latest Cosmetics Regulation Changes

Taiwan has long been working on amending its cosmetic laws. Previously Taiwan Legislative Yuan approved the amendments to "Statute for Control of Cosmetic Hygiene" and then TFDA released the new Act on its official website. The implementation date of this new Act shall be stipulated by Taiwan Executive Yuan. In the interim, Hedy He, Cosmetic Regulatory Editor and Analyst from Chemlinked will be hosting a webinar that outlines the following:

#### Overview of Taiwan Cosmetic Regulations

- Cosmetic definitions and classifications
- Competent authority
- Existing key cosmetic regulations

#### 2. Timeline for Overarching Regulation Changes

#### 3. Latest Regulation Changes

- On Cosmetic Products
- On Obligations of Enterprises
- On Obligations of Government
- Other changes

#### 4. Overall Trend and Impact

Pre-reading Material:

[Taiwan Legislative Yuan Finally Approve Amendments to Statute for Control of Cosmetic Hygiene](#)

[Taiwan Releases Amendments to Statute for Control of Cosmetic Hygiene](#)

## [Tips for Cosmetic Enterprises to Complete Product Notification in Taiwan](#)

It is advised that business involved in Taiwan cosmetic products to join the [webinar](#) on June 27 from 21:30 to 22:30 (GMT +8). This webinar is provided by Chemlink and Cosmetics Alliance is sharing the webinar for member interest only.