Regulatory Essentials – July 7, 2021

Health Updates

Phase I of the Self-Care Framework reaches Canada Gazette I - Proposed Regulations to Improve Natural Health Product Labels

As part of the Self-Care Framework, Health Canada has published Phase I on June 26th which are the proposed regulations to Improve Natural Health Product Labelling for a 70-day public consultation. The objectives of this regulatory proposal are to:

- 1) Improve the self-selection and safe use of NHPs by making labels easier to read with clear and readily accessible information in a consistent format.
- 2) Protect the health and safety of Canadians by reducing the number of preventable harms associated with NHP use; and,
- 3) Introduce amendments to clarify existing provisions of the NHPR.

Cosmetics Alliance is exploring opportunities under this consultation with its Product Compliance & Market Access Committee and its Facility Compliance & Manufacturing Committee to submit comments for the consultation which closes on Saturday, September 4, 2021. If you would like to take part in this these committee meetings, please send an email to regulatory@cosmeticsalliance.ca to join one of these committees.

DEL Bulletin LEPP No. 115 Notice of Publication

On June 29, 2021, the Health Products Compliance Directorate posted two drug Good Manufacturing Practices (GMP) guidance documents to their website. These documents are:

- Cleaning validation guide (GUI-0028) and
- Guide to validation – drugs and supporting activities (GUI-0029)

GUI-0028 and GUI-0029 are revised versions of currently posted documents.

GUI-0029 has an implementation date of **June 29, 2021.**

GUI-0028 has a **phased implementation approach:**

- For drugs introduced for the first time into shared manufacturing facilities: **Dec 29, 2021** (6 months from publication of this guideline).
- For drugs already produced in shared manufacturing facilities the guidance will be implemented, or existing arrangements should be scientifically justified, within:

- **June 29, 2022** (1 year after publication of the guideline) for manufacturers of products for human use including those who manufacture human and veterinary drugs using shared manufacturing facilities.
- **June 29, 2023** (2 years after publication of the guideline) for manufacturers solely producing products for veterinary use.

These documents have been updated to:

- Align with Pharmaceutical Inspection Cooperation Scheme (PIC/S) guidance and international partners;
- Emphasize Quality Risk Management (QRM) Principles;
- Focus on the lifecycle approach to validation and qualification;
- Help industry comply with the regulations as they relate to validation, and;
- Be reformatted using plain language principles in accordance with new Canada.ca requirements.

Health Canada will host a series of webinars to review the revised guidance documents, highlight key changes and to answer any related questions. Invitations for these webinars will be sent in the coming months.

Notification of the 50th Amendment to the IFRA Standards

On June 30th, The International Fragrance Association (IFRA) standards have recently been updated to prohibit the use of Mintlactone (CAS 13341-72-5) as a fragrance ingredient. Please find below more information on the 50th.

the Notification Letter
the final Standard
an updated Index list of all Standards
the Standard Operating Procedure for the implementation of the Amendment

These documents will also be published on the IFRA website (www.ifrafragrance.org).

Information Letter 1120 Quantification of free Formaldehyde in fragrance ingredients and compositions

Below is the harmonized method for the quantification of free formaldehyde in fragrance ingredients and compositions created by the International Fragrance Association (IFRA) Analytical Working Group.

IFRA Analytical Method Formaldehyde

IFRA Analytical Method Quantification of Formaldehyde in Fragrance Ingredients and Composition

Environmental Updates

Various Publications Under the Chemicals Management Plan

Coal Tars

The Final Screening Assessment for Coal Tars and their Distillates was published. The Risk Management Approach for Coal Tars and their Distillates and the proposed order adding coal tars to Schedule 1 of the Canadian Environmental Protection Act, 1999 were also published for a 60-day public comment period ending on August 25, 2021. Please note Coal tar USP used in drugs is prepared by mixing a mass of coal tar with alcohol, polysorbate and washed sand, followed by seven days of mixing. The resulting solution is filtered and diluted with alcohol (U.S. Pharmacopia 2008–2010). The composition of coal tar USP therefore differs significantly from the coal tars considered in this assessment. Use of coal tar therapeutic products is recognized by the United States Food and Drug Administration as Category I (safe and effective) for over-the-counter drug ingredients and for use in the treatment of dandruff, seborrhea and psoriasis. Because these products have been considered acceptable therapeutic treatment options for certain skin conditions by international agencies and because they have been authorized and assigned Drug Identification Numbers (DINs) by Health Canada, their therapeutic use is not considered in this screening assessment.

https://www.canada.ca/en/health-canada/services/chemical-substances/petroleum-sector-stream-approach/stream-0.html

Fact Sheets

Two new fact sheets were published:

1. Use of margins of exposure and risk quotients in risk assessment, and

2. Canadian exposure factors used in human health risk assessments.

In the past, these types of documents were internal reference documents. CA Canada has long advocated for these technical policy documents to be openly available to enhance transparency and predictability with stakeholders.

In many of CA's commentaries on various CMP publications in the past have often been critical of 'not having visibility to these considerations.

The publication of these factsheets represents a significant, positive evolution in regulatory/policy practice. Please also refer to the Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides This document describes how Health Canada's Pest Management Regulatory Agency (PMRA) addresses uncertainty and variability in the mammalian toxicity database in the human health risk assessment of pesticides. The application of uncertainty factors to the most relevant endpoints in the mammalian toxicity database ensures that there is a protective margin between the dose levels that elicit toxicity in laboratory animal studies and the anticipated human exposure. This document also describes how the PMRA addresses the additional 10-fold margin of safety required under certain conditions as specified in the new *Pest Control Products Act* (PCPA). This margin of safety, herein referred to as the PCPA factor, is intended to provide additional protection for infants and children in the risk assessment. This document describes the relevant factors and provides a framework for the application of these factors. https://www.canada.ca/en/health-canada/services/chemical-substances/canada-approach-chemicals/risk-assessment.html

Triazines and Triazole Group

The *Final Screening Assessment for Triazines and Triazole Group* was published. Cosmetic and personal care products use were not identified under the assessment.

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

Government of Canada legislates climate accountability with first net-zero emissions law

For CA’s members with manufacturing facilities this story may of be interest to you:

The Minister of Environment and Climate Change, the Honourable Jonathan Wilkinson, welcomed Royal Assent of the Canadian Net-Zero Emissions Accountability Act, which has become law. It marks the first time a Canadian government has legislated emissions reductions accountability to address climate change, by setting legal requirements on the current government and future governments to plan, report, and course correct on the path to net-zero emissions by or before 2050. More information.

Cosmetics Alliance Updates

Interactive Training Session - Personal Care Product Ingredients and the Canadian Environmental Protection Act (CEPA)

Objectives

This introductory course on CEPA will help you learn and understand:

- our industry's responsibilities under CEPA for cosmetics, drugs and natural health products
- which materials are covered under CEPA which ones are not
- the Chemicals Management Plan (CMP) cycle
- stakeholder notifications (NSNs) and mandatory survey requirements
- what's new under CEPA

Each session includes 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.

Date: Wednesday, July 14, 2021

Time: 2:00 pm - 4:00 pm EDT

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

Register