Regulatory Essentials – June 23, 2021

Health Updates

REP Guidance Documents - May 2021 Updates

The REP FAQ documents has been recently updated and now covers veterinary drugs and disinfectants along with human drugs. Section on Out of Scope has been removed in the updated version and Veterinary drugs and Disinfectants have been added. Please see below for the updated FAQ.

REP FAQ

CESG HC Reference

Third Party Authorization Sample Template

REP Guidance Document

Health Canada Updates the Acne Therapy Monograph

The Natural and Non-prescription Health Products Directorate (NNHPD) has communicated upcoming changes to the Acne Therapy Monograph. The posted monograph has not been updated on-line to-date.

Cosmetics Alliance has prepared a chart comparing previous monograph versions to demonstrate the changes.

The changes are as follows:

The dosage form information has been revised to describe the acceptable dosage forms when used according to monograph requirements. The Acne Therapy monograph is being revised to reintroduce the list of specific dosage forms on the monograph:

- **Acceptable dosage forms for Natural health products (NHPs) and Non-prescription drugs (NPDs):** Aerosol; Cream; Gel; Lotion; Ointment; Paste; Solution; Wipe, medicated.
- **Acceptable dosage forms for NHPs only:** Aerosol, spray; Bar, soap; Foam; Liquid; Soap, liquid; Sponge; Topical liquid.

Directions for use for aerosols and aerosol sprays have also been added to mitigate any potential risk and be consistent with requirements listed on other monographs such as those for sunscreens:

- Do not spray directly onto face. Spray on hands then apply to face
- Avoid inhaling or exposing others to spray.

Cosmetics Alliance Statement on the Publication of Study Finding PFAS in Cosmetics

Background

There has been media coverage in both the U.S. and Canada regarding a recently published study finding various trace levels of PFAS (per- and polyfluoroalkyl substances) in some of the 231 cosmetic products tested – of which 17 were from Canada. The study was published in the Journal of Environmental Science & Technology Letters and is available HERE.

PFAS comprise a class of more than 4,700 chemical compounds with differing chemistries that contain fluorine bonded to carbon, a bond which can make them difficult to break down and so persistent in the environment.

PFAS have been used in lubricants, stain repellents, waterproofing, non-stick coatings, and firefighting foams. They have also been found in consumer products including food packaging, carpeting and cosmetics.

Current Review Under Canada's Chemicals Management Plan (CMP)

Although few PFAS have been studied in detail, some of these have been linked to health effects including increased risk of cancers, reduced immune response and fertility, and altered metabolism and increased obesity. To date, three specific groups of PFAS (PFOS – perfluorooctane sulfonate, PFOA – perfluorooctanoic acid, and LC-PFCAs – long chain perfluorocarboxylic acids) are prohibited in Canada due to their risk to the environment.
As there is a concern that some of the replacement PFAS may also be associated with environmental and human health effects, the Government of Canada, through its world leading Chemicals Management Plan (CMP), is in the process of assessing these substances for their risk to human health and the environment. An update on this assessment process from Environment & Climate Change Canada was provided on April 24, 2021 and is available HERE.
As part of this assessment process, Environment & Climate Change Canada was one of several funders of the recently published study to better understand the presence of PFAS in cosmetics.
The CMP process, which is based upon the use of sound science and risk-assessment, includes the imposition of various risk management measures, if and as required, including restrictions and/or prohibitions. These are used to inform Health Canada's "Hotlist" of restricted and prohibited ingredients for cosmetics which is regularly updated.

Regulation of Cosmetics and Ingredients in Canada

Additionally, it should be noted that the Government of Canada regulates cosmetics both with respect to their ingredients (through the CMP), as well as finished products under the Cosmetic

Regulations and the Food and Drugs Act. More specifically in Canada, all cosmetics products are required to be safe for human health when used as intended.

The Cosmetic Regulations also require that ingredients be listed on the product label using the International Nomenclature for Cosmetic Ingredients (INCI), and a failure to do so as set out in the regulations would be an offense.
Impurities that may be found in a product in trace amounts (i.e., parts per million/billion), whether they are naturally occurring or a by-product of the manufacturing process, are NOT ingredients. They may, however, be subject to limitations set out by Health Canada to ensure they do not present a risk to the health and safety of the consumer.
The study identified PFAS that were both ingredients and impurities.

Cosmetic Industry Commitment to CMP Review Process

Cosmetics Alliance Canada and our member companies have long supported Canada's Chemicals Management Plan and it's science and risk assessment processes. The CMP has been an effective means of continually assessing the environmental and human health safety profiles of ingredients used in our products. We have and will continue to support the work of the CMP, the assessment of PFAS, as well any additional regulatory measures that are required as a result of this process.
We also welcome the contribution to the CMP process of researchers such as those who undertook this study as well as all environmental organizations dedicated to sound science and risk assessment in advancing the protection of our environmental and human health and safety.

FOR FURTHER INFORMATION, PLEASE CONTACT:

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Environmental Updates

Various Publications Under the Chemicals Management Plan

Federal Environmental Quality Guidelines for Aluminum, Selenium & Siloxane-D4

Federal environmental quality guidelines for Siloxane-D4, Selenium, and Aluminum were published. Federal Environmental Quality Guidelines (FEQGs) provide thresholds of acceptable quality in the ambient environment. They are based solely on the toxicological effects or hazards of specific substances or groups of substances. FEQGs serve three functions: first they can be an aid to prevent pollution by providing targets for acceptable environmental quality; second, they can assist in evaluating the significance of concentrations of chemical substances currently found in the environment (monitoring of water, sediment and biological tissue); and third, they can serve as performance measures to assess the effectiveness of risk management

actions for the chemical substance.

FEQG for Aluminium

This factsheet describes the Federal Water Quality Guideline (FWQG) for the protection of aquatic life from adverse effects of aluminium (Al) in freshwaters and is based on total aluminium

FEQG for aluminium

FEQG for Selenium

This factsheet describes the federal tissue quality guidelines for the protection of fish and birds for selenium. FEQGs are not developed for the water, sediment or soil compartments; however, recent water-based guidelines developed in North America are summarized.

FEQG for selenium

FEQG for Siloxane-D4

This factsheet describes the FEQGs for water, sediment, aquatic biota tissue, and wildlife diet to protect aquatic life and mammalian consumers of aquatic life from adverse effects of octamethylcyclotetrasiloxane (D4) (Table 1). It is largely based on the data found in the screening assessment published under Canada's Chemicals Management Plan (Environment Canada, Health Canada (EC, HC) 2008)) as well as additional data and information identified up to January 2018.

FEQG for siloxane-D4

Performance Measurement Evaluation for DEHP

The performance measurement evaluation for DEHP was published. EHP was first assessed by the Government of Canada in 1994, where it was found to be a possible carcinogenic risk to Canadians. Risk management tools [Cosmetic Ingredient Hotlist (2009), the Phthalates Regulations (2011), reporting of DEHP content under the Medical Devices Regulations (2008), and provisions under the Food and Drugs Act (1985)] were established to help reduce DEHP exposures to the general population of Canada in these products.

The performance measurement evaluation concluded that the risk management tools are meeting their intended goals. Biomonitoring data collected from 3 cycles (2007 to 2017) of the Canadian Health Measures Survey (CHMS) shows that Canadians' exposure to DEHP has progressively decreased since risk management tools were implemented.

The evaluation recommends ongoing measurement of DEHP in the CHMS and monitoring of the Phthalates Regulations. Ongoing reporting of DEHP concentrations in medical devices is also recommended.

Complete details on the performance measurement evaluation for DEHP can be found in the Performance Measurement Evaluation for Risk Management of Bis(2-ethylhexyl) phthalate (DEHP), Health Component.

https://www.canada.ca/en/health-canada/services/chemical-substances/performance-measurement-toxic-substances.html#pmer

Post-Consumer Waste Updates

Government releases final Hazardous and Special Products Regulation

The Government of Ontario has finalized the Hazardous and Special Products (HSP) Regulation under the *Resource Recovery and Circular Economy Act, 2016.* The regulation sets requirements for producers that supply designated automotive materials (oil filters, oil contatiners and antifreeze), solvents, paints and coatings, pesticides, fertilizers, mercury-containing devices (barometers, thermometers and thermostats) and pressurized containers (non-refillable and refillable pressurized containers, refillable propane containers) to consumers in Ontario.

The regulation makes producers fully accountable and financially responsible for their products and packaging once they reach their end of life and are disposed; sets mandatory and enforceable requirements for HSP collection systems; and gives producers choices for resource recovery services in a competitive market.

The Resource Productivity and Recovery Authority is the regulator established by the Government of Ontario to enforce the requirements of the HSP Regulation, which requires producers to undertake all or some of the following activities, depending on the material:

- Establish a free collection network for consumers across the province, including for those living in rural and northern communities, as well as First Nation communities

located within and outside the Far North. In larger communities, there must be an accessible network of drop-off locations, while in more remote communities, collection on a call-in basis from municipalities, territorial districts and First Nation reserves is required.
- Manage all collected materials properly by ensuring they are recycled or, in the case of pesticides, disposed of.
- Provide promotion and education materials to increase consumer awareness about how and where to properly recycle or dispose of these products.
- Provide information related to any separate fee charged by the producer or seller in connection to the sale of HSP regarding who imposed the fee and how this fee will be used for resource recovery efforts.
- Register with the Authority and report to the Authority on both supply data and collection and management outcomes, complete a third-party audit of management activities, as well as keep records and meet other requirements.

Producers' collection, promotion, education and management obligations begin on October 1, 2021, following the wind-up of the Municipal Hazardous or Special Waste (MHSW) program operated by Stewardship Ontario on September 30, 2021.

For more information about wind up of the MHSW program and the HSP regulation, visit the webpage.

Provide feedback on RPRA's proposed 2021 Registry fees for Blue Box and Hazardous and Special Products

The Authority is consulting on its proposed 2021 Registry fees for Blue Box materials and Hazardous and Special Products (HSP). These are fees that registrants pay to the Authority annually to cover the Authority's costs related to building and operating the Registry, and compliance and enforcement activities.

In June 2021, the government released the final Blue Box and HSP regulations. The current Blue Box Program operated by Stewardship Ontario on behalf of stewards will transition to the new producer responsibility framework between July 1, 2023 to December 31, 2025.The current Municipal Hazardous or Special Waste (MHSW) Program operated by Stewardship Ontario will wind up September 30, 2021 and transition to the new regulatory framework for resource recovery on October 1, 2021.

Producers obligated under the new Blue Box and HSP regulations will be required to register, report and pay Registry fees to the Authority in 2021. Visit the Blue Box and HSP webpages for more information on the new regulations.

This proposal outlines the proposed 2021 Registry fees for Blue Box and HSP, as well as the methodology for allocating costs across all programs.