# Regulatory Essentials – March 18, 2020

## Health Updates

Quarterly Consumer Product and Cosmetic Reports Summary for Q3 2019-2020

The Consumer and Hazardous Products Safety Directorate regularly receives reports on human health or safety concerns related to consumer products and cosmetics. Consumer products are regulated under the Canada Consumer Product Safety Act, while cosmetics are covered under the Food and Drugs Act.

618 Number of reports received by the Consumer and Hazardous Products Safety Directorate.

Percentage of reports received by product category:

Appliances: 23%; Housewares: 17%; Home and Automobile Maintenance: 16%; Children's Products: 13%; Electronics: 10%; Grooming Products and Accessories: 9%; Clothing, Textiles, and Accessories: 6%; Outdoor Living: 3%; and Sports, Recreation, and Hobby: 3%.

Top 5 product types based on number of reports received

Power Saws: 48; Cosmetics: 45; Electric Ranges or Ovens: 41; Vaping Devices: 22; Telephones or Accessories: 19; Toys: 19.

Top 3 Injury Types

Irritations: 56; Cuts: 41; Burns: 33.

Drug Submission Performance Quarterly Reports

The Drug Submission Review Performance Reports provide detailed metrics about the timeliness of pre-market drug review process against performance service standards. The quarterly report compares five consecutive quarters from October-December 2018 to October-December 2019. The reports are broken down by operational areas. Please see the links to the report below.

BGTD – EN

TPD – EN

NNHPD - EN

Costs Associated with Foreign On-Site Assessments Selected by Health Canada will be built into the Fees in Respect of Drugs and Medical Devices Order

Health Canada's Health Product Inspection Licensing (HPIL) Good Manufacturing Practices (GMP) program conducts a number of foreign on-site GMP assessments annually to obtain evidence to verify that the products being imported into Canada are manufactured at foreign buildings that are GMP compliant.

In recent years, Health Canada has adopted a more sophisticated risk based approach with respect to foreign buildings that manufacture drugs destined for the Canadian market.

As of April 1, 2020, within the *Fees in Respect of Drugs and Medical Devices Order,* Health Canada's cost recovery framework will cover the cost of foreign on-site assessments selected

by Health Canada under the “Building Outside Canada Fee”. Therefore, importers will not be required to reimburse the costs incurred for foreign building assessments that will be selected by Health Canada. The application and licensing process for these Health Canada selected assessments will remain unchanged.

However, assessments requested by an Importer are not covered under this framework. Importers who submit a *Good Manufacturing Practices-Request for Assessment of Foreign Building Form* (FRM-0213) will continue to be invoiced to reimburse the costs incurred as a result of the requested assessment. The application, invoicing and licensing process for these requested assessments will remain unchanged.

Please note, for both Health Canada selected and Importer requested foreign on-site assessments, completion of a *Foreign Building Assessment Services Agreement* (FRM-0214) will still be required.

Importers may be contacted on a bi-annual or quarterly basis with respect to Health Canada selected on-site assessments through the *Good Manufacturing Practices-Notification to Importers of Health Canada Assessment of Foreign Buildings* (FRM-0410).

Canadian Importers are also reminded of their responsibilities related to maintaining foreign buildings on their DEL in accordance with the requirements outlined in *How to demonstrate foreign building compliance with drug good manufacturing practices* (GUI-0080). It is ultimately your responsibility as a Canadian Importer to ensure that drugs manufactured outside of Canada, and imported into Canada, are manufactured in accordance with GMPs.

New Summary Guide for the application of Human Factors to Consumer Products

The U.S. Consumer Product Safety Commission (CPSC) staff and Health Canada’s Consumer and Hazardous Products Safety Directorate (“Health Canada”) have developed this guidance document to help consumer product manufacturers integrate human factors principles into their product development process.

Many product-related injuries can be prevented by better design. Providing the consumer product industry with suggestions on how to apply human factors principles to their products can help lower the number of product-related adverse incidents and reduce costly compliance and enforcement actions. These suggestions can be tailored to meet the needs of a particular product, while understanding that not all practices apply to all products.

*This document is not a rule or regulation and is not meant to create legally enforceable responsibilities*. *This document must be read in conjunction with the applicable legislation. To the extent that this document might be inconsistent with the legislation, the latter shall prevail.*

Please email hc.ccpsa-lcspc.sc@canada.ca or telephone 1-866-662-0666 for a copy of the guidance.

DEL Bulletin No. 66 Introduction of Telecommunication Tools During GMP Inspections

This notice is to inform you that Health Canada intends to introduce the use of certain telecommunication tools during GMP inspections in an effort to assess the feasibility of a virtual or offsite inspection model and to align with other modernization and environmental initiatives.

Beginning in January 2020, Health Canada's GMP inspectors will introduce the use of web-conferencing during certain, pre-selected drug establishment inspections where the regulated activity is any combination of importation, wholesale, and/or distribution.

Key Additional Details:

- Applicable to importers, wholesalers and distribution of drug products
- Health Canada is surveying participants after these virtual inspections to share any suggestions and comments regarding the process
- CA asks for you to share any comments you have in this feedback with us if you experience a virtual inspection

Please let Cosmetics Alliance know if you have any questions.

Presentation for Small Business Webinar

As of April 1, 2020, Health Canada will be implementing revised fees for regulatory services related to drugs and medical devices. In addition, Health Canada will be modifying its existing fee mitigation measures to introduce a comprehensive Small Business Strategy.

Please see the link to the presentation below.

Presentation – EN

ePost Connect – Instructions on How to Verify NNHPD Received Application

Please see below the link to how to verify that NNHPD has Received Your Application through ePost Connect.

Instructions

Presentation Materials for Accelerating the Pace of Chemical Risk Assessment Webinar

The advent of new approach methods (NAMs) for generating safety information on chemicals provides an opportune time to take stock of what chemical risk assessments could/should look like in the 21st century. In 2017, international government entities launched the "Accelerating the Pace of Chemical Risk Assessment (APCRA)" collaboration to develop and apply NAMs for chemical risk assessment. There was public webinar on the results of the current activities from APCRA was held on March 11, 2020.

Below are the presentation Materials.

APCRA – Revisiting and Updating Chemical Groupings

Viant APCRA Daphnia Grouping Public Webinar

Prospective Case Study

Barton-Maclaren APRCA

APCRA Webinar

APCRA Landscape

**Environmental Updates**

Important Emerging Developments – Draft Screening Assessment Reports for Parabens Group, Salicylates Group and Acrylic, Monocyclic and Bicyclic Monoterpenes Group

The Government of Canada published three (3) **Draft Screening Assessment Reports** (DSARs) this weekend under the Canadian Chemicals Management Plan (CMP). The three reports in question pertain to groupings of substances of interest to the cosmetic/personal care sector:

- **Acrylic, Monocyclic and Bicyclic Monoterpenes Group** (including substances such as rose oil, palmarosa oil, geranium oil, coriander oil, rose oil, lemongrass oil, geranyllinalool, mandarin oil, tangerine oil, sweet orange oil, alpha-pinene, turpentine oil, turpentine, fir oil and pine oil)
- **Parabens Group** (including methylparaben, ethylparaben, propylparaben, butylparaben, benzylparaben, isopropyparaben and iso-butylparaben)
- **Salicylates Group** (including wintergreen oil, salicylic acid, homosalate, phenethyl salicylate and *Betula alba* extract)

We regret that based on a review of these publication summaries for all 3 groupings, Health Canada is proposing to conclude that margins of exposures related to some of these substances within these substance groupings in certain cosmetic/personal care uses may present a risk to human health, baed on current conditions/concentrations of use. Corresondingly, it will be proposed that the following substances meet the criteria of Paragraph 64(c) of CEPA, thereby concluding that they *"..are entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitue a danger in Canada to human life or health."*

Specifically:

- In the ***Acrylic, Monocyclic and Bicyclic Monoterpenes Group***, the DSAR will reflect that five (5) of the 15 substances in the grouping (rose, mandarin, tangerine oil used in body moisturizers and/or dietary supplements; and turpentine oil and turpentine used in paint thinners and removers, in addition to use in certain NHP products) present a potential human health risk.
- In the ***Parabens Group***, the DSAR will reflect that the use of methylparaben, propylparaben, butylparaben and iso-butylparaben in certain cosmetics, natrual health products and/or non-prescription drugs may present a potential risk to human health.
- In the ***Salicylates Group***, the DSAR will reflect that the use of wintergreen oil, salicylic acid, and homosalate in certain cosmetic, natural health products and/or non-prescription drugs may present a potential risk to human health.

Finally, although some of these substances are proposed to meet one of the Persistence (P) or Bioaccumulative (B) criteria, based on the available weight of evidence, none of them will be proposed to present an environmental risk.

Although we appreciate that not all substances in each group are proposed to be 'CEPA-toxic', suggesting that it is important to differentiate between substances like parabens when describing the potential risks associated with the group in general – however, unfortunately, it is

likely that these differentiations will be easily and inappropriately generalized – with the broad group being subject to continued scrutiny and potential stigmatization.

Clearly these findings are concerning, thereby warranting significant scientific scrutiny moving forward. Given the interest of these substances to the cosmetic/personal care sector, CA Canada will be monitoring these developments closely and engaging as appropriate in detailed technical reviews of the DSARs once published. If you are interested in participating in the review and potential defense of these ingredients moving forward, we will be initially coordinating this review through our RAIS committee.

We regret that we were not given more advance notice in order to prepare for these publications. However, these publications were anticipated, based on review of the current 'CMP Rolling Action Plan'.

If you have any questions or would like to discuss these developments in further detail, please do not hesitate to contact your CA Regulatory Team (regulatory@cosmeticsalliance.ca)

Acyclic, Monocyclic, and Bicyclic Monoterpenes Group

Salicylates Group

Parabens Group

Risk Assessment Fact Sheets

Consultation on the Proposed Amendments to the Export Control List – Schedule 3 of CEPA

Environment and Climate Change Canada is holding consultations on proposed amendments to the Export Control List (Schedule 3 to the *Canadian Environmental Protection Act, 1999*). These proposed amendments would add to the Export Control List substances for which the use is being prohibited or restricted in Canada and amend the description of certain substances.

Environment and Climate Change Canada prepared a consultation document providing an overview of the proposed amendments. The consultation document is available at: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/consultation-document-export-control-list-2020.html

Interested stakeholders are invited to provide written comments on the proposed amendments by **April 11, 2020** to ec.substancedexportationcontrolee-exportcontrolledsubstance.ec@canada.ca. The input gathered through this process will be used to inform the proposed amendments to the Export Control List.

Over 60 substances are currently on the Export Control List, which is available at: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/export-control-list.html.

**Post-Consumer Waste Updates**

Authority Approves Residual Funds Addendum to MHSW Program Wind-Up Plan

The Authority has approved the Residual Funds Addendum to Stewardship Ontario's (SO) Municipal Hazardous or Special Waste (MHSW) Program Wind-Up Plan. Learn more.

In December, the Authority approved the MHSW Wind-Up Plan with a condition that SO revise sections of the plan that refer to the management of residual funds for consistency with the Minister's direction letter. SO submitted its proposed addendum earlier this year and the Authority consulted on it with stakeholders before approving it in February. The addendum outlines the process of returning residual funds to stewards once the program has ceased operation and all financial obligations have been accounted for. Review the consultation materials, including the consultation report and presentation.

For details on the implementation of the MHSW Wind-Up Plan, visit SO's website

Blue Box preparing for consultation and Webinar Details Below

Stewardship Ontario is working on its proposals for the Blue Box Wind Up Plan that is to be submitted to RPRA by June 30, 2020. Consultation details to be released in the coming weeks.

To participate in the upcoming Blue Box Wind Up Plan consultation webinars.

Stewardship will be hosting three webinar consultations, focused primarily on matters affecting specific stakeholder groups during wind up:

Tuesday, April 7, 2020

- 9:30 - 11:30 a.m.: Steward community
- 1:00 - 3:00 p.m.: Municipalities, First Nations communities and the waste management industry

Wednesday, April 8, 2020

- 1:00 - 3:00 p.m.: Environment non-government organizations and other stakeholders

Please visit the Blue Box Wind Up webpage to learn more and register.

The consultation webinars will be an opportunity to review and comment on how Stewardship Ontario intends to implement the Minister of Environment, Conservation and Parks (MECP) direction outlined in his wind up letter issued on August 15, 2019, including:

- Demonstrating transparency and meaningful consultation.
- Supporting competition and preventing conflict of interest;
- Demonstrating fairness to stewards and protecting consumers; and
- Maintaining program performance.

Other matters of interest to be presented include:

- The proposed process and timelines for transition and related costs;
- The proposed approach to ensure continuity of funding for municipalities;
- Anticipated changes to the method Stewardship Ontario is proposing to determine steward fees during transition; and
- How reserve funds will be applied to offset wind up costs and steward fees.

The transition of the Blue Box Program to full producer responsibility will make industry responsible for both the funding and operation of residential recycling in the province. Your involvement and feedback are essential as we work towards finalizing the Blue Box Wind Up Plan, which will be submitted to the Resource Productivity and Recovery Authority (RPRA) by June 30, 2020. The Minister anticipates RPRA will approve the plan by December 31, 2020.

If you have any questions, please contact us at consultation@stewardshipontario.ca.