Regulatory Essentials – April 15, 2020

Cosmetics Alliance Updates

The Light at the End of the Tunnel: Reflection on COVID-19 Flexibilities – How These Experiences Can Enable The Self-Care Framework

Due to COVID-19 and event restrictions by Federal and Regional authorities, Cosmetics Alliance is cancelling the Spring Regulatory Workshop on May 6. In it's place, we will be offering an online event on June 18 from 1 to 4 pm titled **The Light at the End of the Tunnel: *Reflections on COVID-19 Flexibilities - How These Experiences Can Enable The Self-Care Framework***.

Learn how the interim provisions implemented for COVID-19 foreshadow how certain elements of the Self-Care Framework may be operationalized. Connect with the Director Generals of the NNHPD, CHPSD, and ROEB along with Cosmetics Alliance Staff in our Q&A session to explore these important considerations as we continue to help shape the Self-Care Framework.

Join us in finding the light at the end of the tunnel! **Agenda and registration details to follow.**

Cosmetic Alliance Launches Manufacturing Exchange Program

Cosmetics Alliance, along with the Canadian Consumer Specialty Products Association and the Canadian Distillers Association, are pleased to launch the *Hand-Sanitizer Manufacturing Exchange.*

At the urging of Health Canada and Canadian Manufacturing & Exporters, we have been encouraged to assist in matching manufacturers with suppliers of ingredients, components and supportive services to maximize the domestic production of all-important hand-sanitizers during the COVID-19 pandemic.

If your company has manufacturing capacity but requires ingredients, components or supportive services; or if you have ingredients, components or supportive services available this Manufacturing Exchange can help make the match to GET the JOB DONE!

NOTE: Given that time and effort are also in demand, if you belong to more than one participating trade association you need only access the *Exchange* through one website as “we are all in this together”!

Details can be found here.

Health Updates

Interim, Guide on the Product of Ethanol for Use in Alcohol-Based Sanitizers

Numerous Canadian entities have expressed interest in providing additional and/or alternate sources of ethanol (also known as anhydrous alcohol, ethyl alcohol, or grain alcohol) for use in the production of hand sanitizers to support the national response to the supply shortage of alcohol based hand sanitizers during the COVID-19 pandemic.

To help with this shift, Health Canada has developed the attached guide which provides information on the use of ethanol as an ingredient in alcohol-based hand sanitizers sold in Canada. This document builds on the Guide on Health Canada's Interim Expedited Licensing Approach for the Production and Distribution of Alcohol-Based Hand Sanitizers released last week to help businesses navigate the natural health product (NHP) application process to obtain the required authorizations.

The attached guide includes:

- Acceptable quality grades
- The recommended formula for the production of hand sanitizers
- Excise tax implications
- Contact information in case you have questions

This Guide will also be available on our website later today.

Health Canada would like to thank those who contributed to the development of this Guide and all of the businesses who have offered their support in response to the current shortage of alcohol-based hand sanitizers.

Please visit HC website for information on the national response to COVID 19 and ways that Canadian businesses can help.

Interim Guide on Ethanol – EN

Interim Guide on Ethanol - FR

DEL Bulletin 80 – Revised Drug Establishment Licenses

Revised fees for drugs and medical device will be implemented on April 1, 2020 and have been published in Canada Gazette, Part II on May 29, 2019. To implement the new fees, new policies have been established including the pause-the-clock policy and additional application process improvements have been made for the review of DEL applications.

Management of Applications and Performance for Drug Establishment Licences (GUI-0127)

New policies (including the pause-the-clock policy) and additional application process improvements are included in GUI-0127 and will be implemented on April 1, 2020. Health Canada (HC) is pleased to share with you the final version of the Management of Applications and Performance for Drug Establishment Licences (GUI-0127): https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/management-applications-performance-drug-establishment-licences-0127.html

Guidance on Drug Establishment Licences (GUI-0002)

The Guidance on Drug Establishment Licences (GUI-0002) has been updated in preparation for the April 1, 2020 implementation and includes the removal of all reference to DEL fees. Fee and

payment information is now available in a standalone guide, *Fees for the Review of Human and Veterinary Drug Establishment Licence Applications.* The following changes were also made:

- ✓ Section 3 was revised to improve the clarity of the requirements that pertain to the Sterilization of Raw Materials and Packaging Material
- ✓ Section 6 was revised to clarify that each DEL foreign building annex (for importers) is specific to one domestic building

The revised GUI-0002 is located here: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drug-establishment-licences-drug-establishment-licensing-fees-0002.html

Drug Establishment Licence Application Form and Instructions (FRM-0033)

The Drug Establishment Licence Application: Forms and Instructions (FRM-0033) was also revised to:

- ✓ Reflect components of the new cost recovery regime as per the *Fees in Respect of Drugs and Medical Device Orde*r, including fee mitigation measures for small businesses and fee exemptions
- ✓ Include updates to category "Prescription Drug List (PDL), Schedule G, Narcotics, and/or Drug containing Cannabis" which came into force October 2018

The revised FMR-0033 is located here: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/drug-establishment-licence-application-instructions-0033.html

Guidance document on the application for a certificate of a pharmaceutical product and good manufacturing practice certificate (GUI-0024)

The guidance document on the application for a certificate of a pharmaceutical product and good manufacturing practice certificate (GUI-0024) was also revised, changes include:

- ✓ Revised throughout for improved flow and clarity
- ✓ Updated to reflect the new fees coming into effect April 1, 2020.

The revised GUI-0024 is located here: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-application-certificate-pharmaceutical-product-0024.html

If you have any questions, please email: hc.del.questions-lepp.sc@canada.ca.

Guidance Documents on Disinfectants

The "dual-use" transition will take effect April 1, 2020. The French guidance documents will follow shortly, and as federal communication efforts are prioritizing the COVID-19 emergency

response, Health Canada will provide future updates on when the guidance documents will be posted online.

A a high-level summary of responses to the feedback received on the guidance documents has been developed. Many of your recommendations were either made exactly as proposed or general revisions were made. Below is a summary of how your proposed changes were considered (i.e., which ones resulted in changes to the documents and which ones did not).

The following have been addressed with changes made to the guidance documents:

- Submission of summary reports – Changes were made to emphasize that i) summary reports submissions are not mandatory for disinfectant applications; ii) they will not be used in isolation to screen out applications; and iii) applications without a summary report will not trigger the issuance of a Screening Deficiency Notice (SDN).
- Effective date / request for a 90-day implementation delay – Changes were made to emphasize that testing conducted under either the 2020 updates or the previous versions of the guidance documents (2014 and 2018) will be acceptable. Studies signed off prior to the effective date of the previous version of the guidance document (2018) will be assessed at Health Canada's discretion for their acceptability under the updated data requirements.
- Reference to European Chemicals Agency (ECHA) - Given references made to the US EPA and Australian TGA, the guidance documents now include references to the European central regulatory agency as well, without European specific efficacy data requirements added.

The following recommendations were not incorporated in the guidance documents:

- For comment beyond the scope of the current guidance document revisions, e.g., the addition of air and water sanitizers and the filing pathway for sanitizer-only products, no changes were made.
- For those relating to potential future revisions to the US EPA 810 guidelines, finalized information has not yet been available for consideration, so no revisions were made.
- For the comment on specific reference to 2019 US EPA FAQ document, this has not been included because it is an evergreen third party document. Applicants may reference these at their discretion. Note that the guidance documents do reference "US EPA 810 guidelines as well as additional stand-alone methods, procedures and guidance".
- For the comment on LONOs issuance, the guidance documents do not include LONOs as a requirement for incidental additives, while clarifications of maximum in-use concentrations have already been incorporated. The Food Directorate indicated that they still issue on request LONOs.

Currently, sanitizer only products are not captured under the definitions in the *Food and Drug Act*, and therefore cannot be regulated as drugs. As of April 1st, NNHPD will be accepting applications for dual-use indirect COVID-19 claims. This includes requests for products that are regulated by PMRA. Surface (hard and soft) products that are primarily disinfectants with secondary sanitizer claims. Health Canada is currently expediting only those applications for products with claims related to COVID-19.

While NNHPD is committed to reviewing these types of applications with expedited service standards, the evidence and review standards against the regulations and associated guidance

have not changed. The standards of evidence will remain the same for all applications to ensure safety, efficacy and quality of these products for Canadians.

1. Disinfectant Drugs
2. Safety and Efficacy Requirements
3. Management of Disinfectant Drug Applications

DEL Bulletin 81 – Health Canada Launches a Pilot to Implement the Electronic Issuance of Drug Establishment Licenses

Health Canada (HC) recognizes that the COVID-19 pandemic has had a significant impact on business operations, within both the pharmaceutical industry as well as governments.

To help ensure critical business lines such as drug establishment licensing can continue with minimal delays to regulated parties, effective Thursday, April 2nd, 2020, HC is launching a pilot to implement the electronic issuance of DELs via email with electronic signatures and will no longer be sending paper copies of DELs by mail.

Why is HC launching this pilot now?

This pilot to implement the electronic issuance of DELs (i.e. issue "e-DELs") will offer the following benefits:

- ✓ Minimal disruption to the issuance of DELs to regulated parties amid the current COVID-19 situation;
- ✓ A "greener" process for issuing e-DELs with the elimination of paper usage;
- ✓ More efficient, stream-lined and cost-effective process to issue e-DELs so regulated parties can access their e-DELs in a more expeditious manner;
- ✓ Added security and privacy features, since the type of electronic signatures used for e-DELs have added encryption with the use of public keys and digital certificates.

How long will this pilot last and where do I send feedback during its implementation?

To help ensure drug establishment licensing can continue with minimal delays to regulated parties especially amid the current COVID-19 situation, HC is launching this pilot immediately and for an indefinite period of time but will monitor its implementation so that adjustments can be made if required. Please share any feedback you may have regarding this pilot implementation that could help ensure an effective, long-term process, by writing to hc.del.questions-lepp.sc@canada.ca.

DEL Bulletin LEPP No. 82 Health Canada is taking action to quickly respond to potential drug shortages during the COVID-19 pandemic

There is an unprecedented demand and urgent need for access to drugs during the COVID-19 pandemic. On March 30, 2020, the Minister of Health signed the *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19*. The interim order (IO) allows certain drugs that may not fully meet regulatory requirements to be imported and sold in Canada.

An IO is one of the fastest mechanisms available to address large-scale public health emergencies, without following the usual regulatory processes. Further information on this Interim Order can be found in the Explanatory Note.

Drugs that are eligible under the interim order

Drugs included on the *List of Drugs for Exceptional Importation and Sale* are called "**designated drugs**" and are eligible for the exceptional importation and sale provisions provided for in the Interim Order. The list, which will be updated as required, is incorporated by reference in the IO and is maintained by Health Canada.

Criteria for adding a drug to the *List of Drugs for Exceptional Importation and Sale*

At this time, drugs that meet both of the following criteria will be considered for addition to the list of designated drugs:

- **Significant shortage:** Only drugs in shortage designated as a Tier 3 shortage are eligible, as defined by the Multi-Stakeholder Steering Committee Protocol on Notification of Drug Shortages.
- **Good manufacturing practices compliance:** Drugs must be manufactured in accordance with GMP requirements. Companies that are importing and selling the designated drugs must have a Drug Establishment Licence (DEL):
    - The DEL must cover the importation of the drug under the applicable category and dosage form.
    - Buildings outside Canada must be listed in the Foreign Annex of the importer's DEL for the applicable activity, category of drugs and dosage.

NOTE: Other criteria may also be considered by Health Canada in adding products to the list of designated drugs.

Visit the drug shortages website and sign up for daily notifications of drug shortages.

Tier 3 Drug Shortages

Tier 3 shortages are those that have the greatest potential impact on Canada's drug supply and health care system. Impact is based on low availability of alternative supplies, ingredients or therapies.

The Tier Assignment Committee (TAC), which includes federal and provincial/territorial governments, healthcare professionals, and industry stakeholders, makes recommendations on the tier assignment of drug shortages. The TAC assessment includes:

- a review of the information gathered on the shortage issue, and
- a thorough discussion on its potential impact and next steps.

Note: At this time, only drugs on this list are eligible to be added to the List of Drugs for Exceptional Importation and Sale.

How to propose an addition to the list of designated drugs

The following actions must be taken to propose an addition to the list of designated drugs.

Step 1: Submit proposal

To add a drug in a Tier 3 shortage to the List of Drugs for Exceptional Importation and Sale, please fill out the attached form and email it to hc.ds-iopropau-pm.sc@canada.ca.

Health Canada will assess the proposal and may contact you to clarify information or to ask for product-specific information. HC review depends on a number of factors, including but not limited to product type and availability of supply.

Note: We may also add a product to the list without receiving a proposal.

Step 2: Ensure compliance

Health Canada must have evidence that foreign buildings which fabricate, package/label and test designated drugs and their active pharmaceutical ingredients (API) are GMP compliant for the applicable activity, category of drugs and dosage form.

Health Canada expects that, in many cases, designated drugs will be sourced from foreign buildings that are already listed on the:

- Foreign Building Annex of the Canadian importer's DEL (with the applicable activity, category of drugs and dosage form), and
- the API annex.

For these cases, there will be no need for additional foreign building compliance information, unless requested by Health Canada.

In cases where the foreign buildings are not currently listed on the Foreign Building Annexe of the Canadian importer's DEL, Health Canada will clearly communicate foreign building compliance evidence and documentation requirements.

A foreign building will be considered compliant if:

- It is currently determined to be compliant by Health Canada
- It is currently determined to be compliant by a trusted regulatory partner for the applicable activity, category of drugs and dosage form.

Other examples of foreign building compliance may be accepted on a case-by-case basis. Health Canada will expedite the approval process to amend the DEL.

How to import and sell designated drugs

Step 1: Approval to import and sell designated drugs

Canadian importers will be permitted to import and sell designated drugs once:

- the drug is on the List of Drugs for Exceptional Importation and Sale
- their DEL Foreign Building Annex and API building annex have been amended as required

Although the Canadian importer is permitted to sell designated drugs once included on the list of designated drugs, they must still notify Health Canada when designated drugs are imported.

Step 2: Pre-importation notification requirements

Importers must notify Health Canada at least **5 calendar days** before the day they import a designated drug. They must do so by sending an email to hc.ds-ionotifau-pm.sc@canada.ca. The email must contain the following information:

- importer's name and contact information
- name, address and contact information of each fabricator, packager/labeller and tester involved with the drug
- brand name of the drug to be imported
- medicinal ingredient(s)
- dosage form
- strength
- route of administration
- identifying code
- detailed description of the conditions of use of the drug
- intended port of entry into Canada
- intended date of arrival into Canada
- customs identification number for the shipment
- total quantity of drug to be imported

Regulatory requirements for selling designated drugs

During the application of the interim order, Canadian importers may bring designated drugs into the country without meeting all the requirements of the *Food and Drug Regulations* (FDR). However, Health Canada wishes to highlight the following:

- Importers are still obligated to report all adverse drug reactions (C.01.016 to C.01.019).
- Hospitals/Medical Professionals must continue to report serious adverse drug reactions (C.01.020.1).
- Existing requirements and controls for prescription drugs will remain in effect (C.01.040.3 to C.01.049).
- Importers must report all recalls (C.01.051).
- Importers must adhere to all DEL requirements in Division 1A of the FDR, including listing foreign buildings on their licence (this includes considerations applicable for the active pharmaceutical ingredient (API), intermediates, and finished dosage forms).
- Importers must fulfill most good manufacturing practices (GMP) requirements, as outlined in Division 2 of the FDR, with some exceptions (see the next section).

Importers should note the exemptions to certain sections in Part A of the FDR, as indicated in the interim order, along with the requirements that remain in effect including:

- Obligations for security packaging when the drug is intended for sale to the general public (A.01.065)
- Provisions relating to advertising (A.01.067) and sale (A.01.068)

Interim Order changes to GMP requirements for Canadian importers

Canadian importers of designated drugs must follow the same GMP requirements that apply to all imported drugs. The interim order (IO) provides some exceptions.

Keeping records

Importers do not need to maintain records specified in Section C.02.020 (1) parts a, b and d of the *Food and Drug Regulations* at the importer's building address in Canada, such as:

- master production documents
- validation reports
- executed batch records
- stability documentation

However, this information must be made available to Health Canada upon request.

Written agreements

Canadian importers should ensure they have access to written agreements when importing designated drugs.

Release process

Canadian importers can base the release of a designated drug on:

- Certificates of Analysis and Certificates of Manufacture (or equivalent) from buildings listed on the DEL foreign building annex. All release testing must be completed prior to release of product.
- Confirmation that the drug has been transported and stored properly.
- Visual inspection of the drug to confirm its identity. Visual inspection should include:
    - product labelling
    - dosage form
    - physical measurements (for example, dimensions, volume), if applicable

Release documentation should clearly indicate that the drug was released under the *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19*.

HC Disinfectant Sanitizing Form – EN

HC Disinfectant Sanitizing Form – FR

HC Form Proposal Exceptional Import Drugs - EN

HC Form Proposal Exceptional Import Drugs - FR

TDG Announcement for Next COVID Bulletin

Transport Canada Issues Temporary Certificate to Enable the Facilitated Transport of Hand Sanitizers (and other essential medical supplies) During the CoVID-19 Crisis (Issued: April 3, 2020)

- The handling and transport of hand sanitizers (by virtue of the fact that they contain high concentration of ethyl alcohol/ethanol or isopropyl alcohol/isopropanol or mixed alcohols) are typically subject to Transport of Dangerous Goods Provisions
- Under Temporary Certificate Number: TU-0752, parties handling, offering for transport, transporting or importing hand sanitizers (in a road vehicle, railway, vehicle or vessel between points in Canada) will be able to take advantage of the temporary emergency provisions as outlined.
- These special provisions apply to the handling and transport of product when the capacity of the means of containment is less than or equal to 30 L OR between 30 L and less than or equal to 450L. There are also specific conditions for combination packages and small volume units (i.e. less than 5L)
- These temporary, special provisions take effect April 3, 2020, and will remain into effect until Sept 30, 2020 (OR the day in which this temporary certificate is cancelled by Transport Canada)

These provisions should make it easier to facilitate transport and distribution of qualified alcohol-based hand sanitizers in Canada.

Transportation Dangerous Goods Directorate – EN

Transportation Dangerous Goods Directorate - FR

Updated Antiseptic Skin Cleanser Monograph

The Antiseptic Skin Cleansers Monograph has been updated on March 20, 2020. Please see below for the changes to the monograph from the old version.

Changes from 2018 to 2020 Monograph

Foreword: Change from Feb 9, 2016 to Dec 7, 2018

Table 1:

- Isopropanol upper limit changed from 70% to 75%
- Addition of WHO 2010 and WHO 2009 endnotes

References:

- Addition of WHO 2010
- Modification to WHO 2009

Antiseptic Skin Cleanser Monograph – EN

Antiseptic Skin Cleanser Monograph – FR

DEL Bulletin LEPP No. 83 Health Canada COVID-19 Update for Health Product Licence Holders

Health Canada is seeking your support to help ensure that Canadians are able to access the health products they need during this time of crisis.

Since COVID-19 emerged, Health Canada has been working to:

- prioritize and expedite the review of COVID-19-related submissions while maintaining all essential service standards;
- identify and track all clinical trials, potential diagnostic tests, treatments, and vaccines;
- harmonize data requirements for COVID-19 submissions with international regulatory partners;
- implement interim regulatory measures to expedite access to personal protective equipment, diagnostic tests, and disinfectants and hand sanitizers;
- advance other short-term regulatory and legislative measures to quickly respond to key issues, such as anticipating and addressing drug and medical device shortages; and
- consider temporary measures for operational and regulatory flexibility during the COVID-19 crisis.

While these are important steps, we can accomplish more with your help. We have identified several activities where you may be able to contribute:

- submit any promising COVID-19-related health products, with corresponding scientific evidence, so we can prioritize and review them as quickly as possible;
- consider Canadian sites for any clinical trial or investigational testing related to COVID-19; and
- identify any production capacity you have that could be used for manufacturing personal protective equipment, ventilators, or hand sanitizers and disinfectants.

If you can contribute in these areas, Health Canada encourages you to visit their website. HC has consolidated their information on industry topics related to COVID-19 here: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry.html.

Key topics on this page include:

- Expedited access to personal protective equipment, ventilators, diagnostic tests, disinfectants and hand sanitizers
- How to apply for authorization for the sale of health products, and other relevant guidance and resources
- Lists of COVID-19-related clinical trials and investigational testing authorized in Canada
- Lists of COVID-19-related applications received and products authorized
- Who to contact for help

HC recognizes that many of you have questions about selling and supplying health products to help fight this COVID-19 crisis. As Health Canada is receiving a significant volume of questions from stakeholders, health care professionals and Canadians, they urge you to visit this new website before contacting HC for information about health product regulatory authorization. An additional list of online resources is also included below.

This is an unprecedented public health crisis in Canadian history. Your cooperation and collaboration is crucial to help HC address this challenge and meet the health needs of Canadians.

Environmental Updates

Extension to the Consultation Period on Amendments to the ECL

Environment and Climate Change Canada initiated consultations on proposed amendments to the Export Control List (Schedule 3 to the *Canadian Environmental Protection Act, 1999*) on March 12, 2020. 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.

This consultation period was set to close on April 11, 2020, however Environment and Climate Change Canada recognizes the impacts faced by Canadian industry in light of recent and current events. Understanding the importance of stakeholder engagement, the public comment period is hereby extended until May 22, 2020 for the proposed amendments to the Export Control List.

Please note that the proposed amendments to the Export Control List will also be published in Part I of the *Canada Gazette* later on and will provide for an additional 60-day comment period.

Substances listed to the Export Control List are subject to the *Export of Substances on the Export Control List Regulations.* More information on these regulations is available at: https://canada.ca/export-controlled-substance. Substances listed to the Export Control List are subject to the *Export of Substances on the Export Control List Regulations.* More information on these regulations is available at: https://canada.ca/export-controlled-substance

Initial Technical Review - Parabens, Salicylates and Monoterpenes Groupings DSARs and RM Scopes (published Mar 14, 2020)

As reported previously, the Government of Canada published a series of Draft Screening Assessment Reports (DSARs) and corresponding Risk Management Scoping Documents (RM Scopes) pertaining to 3 Substances Groupings being assessed under the Canadian Chemicals Management Plan (CMP).

- Parabens Grouping (7 discrete parabens)
- Salicylates Grouping (5 substances)
- Acyclic, Monocyclic and Bicyclic Monoterpenes Subgrouping (15 of 76 substances in the Terpenes and Terpenoids Grouping)

Many of the substances included in these DSARs/RM Scopes are of significant interest from a cosmetic and personal care perspective (low-risk drugs/NHPs). Furthermore, the proposed findings, as previously reported, are also highly significant in that many of these substances of interest are proposed to be found 'CEPA-Toxic' based on human health considerations.

We are pleased to provide the Issue Summary below, which provides a brief overview of the proposed conclusions and potential implications for our industry; along with some preliminary initial impressions of some of the scientific commentary that we believe is necessary in response to these publications. Based on this review, we believe that there is significant opportunity for clarification and/or improvement in the risk assessments underpinning these proposed findings, and as such CA Canada will be consolidating a detailed risk- and science-based commentary to provide as input in support of these draft findings.

We will be working with our Risk Assessment and Ingredient Safety Committee on commentary.

Finally, please note that we have already reached out to our international colleagues at CE and PCPC; as well as IFRA, US FCA and RIFM, to ensure that we are collectively coordinated in our respective approaches to this commentary. We are also collaborating with CCSPA, CHP Canada and FCPC to ensure that we can reinforce and reflect any of their anticipated commentary regarding these publications.

Lastly, we are still awaiting OFFICIAL CONFIRMATION of the extension to the published 60-day comment window corresponding to these draft publications. Given that these were published just as the CoVID-19 pandemic and related 'States of Emergencies" began escalating, officials do recognize that further time will be needed to re-focus efforts on these considerations. To this end, we have secured informal agreement from officials that they will be open to receiving comments beyond the published comment window and are presently operating with the understanding that formally the window will likely be extended by an additional month (in line with what was recently confirmed regarding the State of Science Report regarding plastics pollution). Of course, as with all Canadian CMP draft publications, officials are always open for science engagement between the publications of the DSARs and FSARs and we will be taking full advantage of these flexibilities, as necessary.

Look forward to discussing these DSARs and RM Scopes with you over the next couple of months.

Please do not hesitate to reach out to your CA Regulatory Team should you wish to discuss this summary or have any clarifications regarding the attached overview (regulatory@cosmeticsalliance.ca).

Member Issue Update – Initial Review

Post-Consumer Waste Updates

RPRA Extends the 2019 Datacall Reporting Period

As part of RPRA's response to the COVID-19 pandemic, the Authority has extended the deadline for 2019 Datacall submissions to **Friday, May 29, 2020.** The Datacall is the source of data for determining the net Blue Box system cost and for allocating funding under the Blue Box Program Plan. Each Ontario program providing recycling services must complete the Datacall to be eligible for Blue Box funding. Learn more

Minister grants extension for submitting Blue Box Program Transition Plan to RPRA

To ensure meaningful consultations can still occur with all Blue Box stakeholders, RPRA asked the Minister of Environment, Conservation and Parks for a 60-day extension for submitting the transition plan to the Resource Productivity and Recovery Authority (RRPA). The Minister has since granted Stewardship Ontario's extension request in a letter received this week.

This extension allows us to:

- Extend the stakeholder feedback deadline on transition plan proposals to **July 8, 2020**.
- Submit the transition plan to RPRA no later than **August 31, 2020** (rather than June 30, 2020).

The Minister still anticipate RPRA will approve the plan no later than **December 31, 2020**, meaning there will be **no delay in the transition timelines originally set out** in the Minister's August 2019 direction letter.

RPRA continue to assess the pandemic situation and will reschedule the consultation webinars at an appropriate time.

The consultation materials going to be presented this week will be made available to stakeholders shortly so that they can be reviewed. Once these materials are available, RPRA will invite stakeholders to send their questions so that RPRA can respond to them virtually.

RPRA will also be reaching out to stakeholder group associations to schedule meetings and discuss initial feedback on the materials before the rescheduled consultation webinars.

Please contact us with questions at consultation@stewardshipontario.ca.

Other Update

Word from Ad Standards President

Please the note from the Ad Standards President:

It was just a few months ago that we were sending out best wishes for 2020; now my wish is this find you both healthy and safe.

We as an industry have a history of rising to the occasion and coming together to overcome challenges, and COVID 19 will be no different. Examples of community compassion and care, newly dubbed “caremongering”, abound. These stories provide hope, as does the thought that our pets and children are receiving all the family time they can handle!

Now more than ever, our mission of helping ensure that Canadian advertising is “Truthful, Fair and Accurate” is important. More Canadians are engaging with all forms of media as we spend extra time at home, and what we are all seeing during this time truly matters. Advertisers and agencies are pivoting, adapting and working hard to make certain their content is appropriate and helpful in the current global climate. It is the ideal time to connect and advertise responsibly.

To that end, in response to recent COVID-19 related advertising, we've created an advisory to remind advertisers about their claim substantiation obligations, in particular in the context of health and scientific claims:

Coronavirus disease 2019 (COVID-19) Claims and a Reminder About Substantiating Advertising Claims

Further to this, the International Council for Ad Self Regulation (ICAS), or which Ad Standards is a member, has also released a similar advisory, entitled “ICAS, EASA and CONARED

Statement on the Importance of Responsible Advertising and COVID-19.”

If you have any questions about either advisory, please don’t hesitate to contact us.

Some Additional Updates

- Ad Standards employees started working from home in a part-time capacity two years ago and have now switched to working remotely full-time. It is business as usual for us,

which means we continue to support our members, preclearance remains completely available, we are accepting and actively handling consumer complaints, and our Standards Council meetings continue as scheduled (remotely).

- Our upcoming *Code* seminars, previously scheduled for April 20 (Toronto) and April 22 (Montreal), have transitioned from live events to an online Webinar, which will run on April 20. Learn more and register: https://www.eventbrite.ca/e/webinar-introduction-to-the-canadian-code-of-advertising-standards-registration-95425262529
- Our Annual General Meeting will be held (remotely) on April 30. Members can expect to receive information about proxies and login information next week.
- We recently had an online employee support session focused on what we can do for ourselves in times of uncertainty. I just wanted to share three simple takeaways with you here:
    1. **Physical Exercise**: try to take on a physical activity each day (e.g. yoga, stretching, weightlifting, etc.);
    2. **Mental Exploration**: each day, do at least 20 minutes of something that is creative and fun (e.g. painting/drawing, practice with a musical instrument, learn a new language, etc.);
    3. **Emotional Connection**: connect with someone daily, whether that be a family member, friend, or someone you haven't heard from in awhile. Social distancing does not require emotional distancing. We are all becoming familiar with various online apps for group meetings and have returned to phone calls and video conferences. Reaching out to business colleagues in ways other than email is also a nice diversion from the onslaught of unsettling news we seem to receive regularly (last little tip, take news breaks).

On a personal note, I would love to have a virtual coffee with you – just let me know when! If you like to video chat, I promise to only be wearing my pj's on the bottom :)

As Canadians, we all have a responsibility to Flatten the Curve – we can do this together!