Regulatory Essentials – July 21, 2021

Health Updates

Updated Recent Development - Valisure Report (Sunscreens) - Information Requests from NNHPD – Benzene

The Natural and Non-prescription Health Products Directorate's (NNHPD) Risk Management Division (RMD) has issued a follow-up request to a sub-set of stakeholders resulting from Cosmetics Alliance's collaboration with the NNHPD to provide a valuable input from stakeholders.

We understand this request has not expanded to stakeholders outside of those identified in the Valisure Report. At this time, based on our discussions with RMD, this is an information gathering activity to identify potential root-causes across products and stakeholders indicated in the Valisure report. Input from this small-scale exercise, we understand, may ultimately inform the scope for any broader scale follow-up Health Canada may potentially pursue (if any) in the future. Therefore, it is in our members' interest to engage, if possible, with this information survey.

If your products are approved for sale in Canada but not yet marketed, we recommend you respond to Health Canada regardless, indicating such in your response. If this is the case, you may also wish to initiate investigations, etc. for the products in case they do end up being marketed in Canada at any point, as the root cause investigations may become valuable at some point in Canada or in the United States.

NEXT STEPS

- We recommend each stakeholder who has received this message respond accordingly.
- The turn around is tight, therefore, do ask for an extension with a proposed timeline if you require more time to complete the request.

CHPSD Releases Pre-Consultation Stakeholder Engagement Notice – Cosmetic Modernization Reforms

During our Spring Virtual Regulatory Workshop on June 1, 2021, the Consumer and Hazardous Products Safety Directorate (CHPSD) announced as part of the Forward Regulatory Plan for 2021-2023 (released on April 2021) their plans to amend the Cosmetic Regulations. Specifically, CHPSD indicated that the proposed amendments would likely:

- Introduce a requirement for the disclosure of specific fragrance allergens on the product label; and
- Include provisions to enhance regulatory oversight for cosmetics

Health Canada is expecting to proceed with these cosmetic modernization regulatory reforms in 2022. As part of their amendment process, the CHPSD has committed to engage with a pre-consultation process, to seek preliminary input from stakeholders as to their early thinking on some of the technical and administrative proposals they are currently contemplating for Gazetting in 2022.

Pre-Consultation Notice

The Notice provides a brief overview of the key elements under consideration, and includes a detailed Questionnaire for interested stakeholders to complete.

Below is a summary of primary technical elements featured in the pre-consultation notice:

- Disclosure of fragrance allergens (labelling)
- Clarifications in definitions/terminology (including, manufacturing, importer, distributor)
- Clarifying the need to use INCI in supporting cosmetic notifications (current INCI requirements are focused on labelling; looking to extend requirement to the notification process itself, to allow for consistency between notifications and labels)
- Establishing a notification backstop that will clarify 'regulatory actions' in relation to Section 30 (1):

Every manufacturer and importer shall provide the Minister with the following documents, at the latest 10 days after the manufacturer or importer first sells a cosmetic:

- **(a)** a notification on a form obtained from the Minister and signed by the manufacturer or importer, as the case may be, or a person authorized on their behalf, advising whether they intend to continue sales of the cosmetic in Canada and including the information specified in subsection (2); and

- **(b)** if the labels and inserts used in conjunction with the cosmetic require the information set out in any of sections 22 to 24, a copy or facsimile of the labels and inserts

and (2) of the Regulation:

The following is the information required for the purpose of paragraph (1)(a):

- **(a)** the name and address of the manufacturer that appears on the label of the cosmetic in accordance with section 20;

- **(b)** the name under which the cosmetic is sold;

- **(c)** the function of the cosmetic;

- **(d)** a list of the cosmetic's ingredients and, for each ingredient, either its exact concentration or the concentration range that includes the concentration of that ingredient, the latter of which may only be indicated by setting out either the applicable concentration range set out in column 1 of the table to this section or the number in column 2 that corresponds to the applicable concentration range set out in column 1;

- **(e)** the form of the cosmetic;

- **(f)** the name and address in Canada of the manufacturer, importer or distributor;

- **(g)** if the cosmetic was not manufactured or formulated by the person whose name appears on the label, the name and address of the person who manufactured or formulated it; and

- **(h)** the name and title of the person who signed the notification referred to in paragraph (1)(a).

- Refinements to concentration reporting for CNF concentration listings (to allow for more gradation/delineation, particularly at higher concentrations of use)
- Extension of 'evidence of safety' activities (Section 29) (1), (2), and (3); extending beyond just manufacturers (i.e., obligations for importer/distributor):

29 (1) The Minister may request in writing that a manufacturer submit to the Minister, on or before a specified day, evidence to establish the safety of a cosmetic under the recommended or the normal conditions of use.

(2) A manufacturer who does not submit the evidence requested under subsection (1) shall cease to sell the cosmetic after the day specified in the request.

(3) If the Minister determines that the evidence submitted by a manufacturer under subsection (1) is not sufficient, the Minister must notify the manufacturer in writing to that effect, and the manufacturer must cease to sell the cosmetic until the manufacturer

- Few administrative updates (editorials and formatting)

The pre-consultation will be open for **45 days (ending August 30th)**. CA Canada has already indicated that this deadline falls right in the middle of the summer holiday season for the stakeholder base, and as such has already asked for practical consideration in this regard. Although the formal consultation window is unlikely to change, we understand that HC has acknowledged to CA Canada that some small degree of latitude with this deadline will be contemplated, where reasonable (upon request).

CA's goal is to ensure these amendments do not undermine the Self-Care Framework. CA will be working with membership and Health Canada to ensure the amendments are in line with the principles of the Self-care Framework.

We wanted to inform our membership of these important developments. We encourage our membership to review the pre-consultation notice and to respond to the accompanying questionnaire as appropriate. CA will be engaging with our Product Compliance & Market Access and Facility Compliance & Manufacturing Committees to consolidate a comprehensive industry response on behalf of our members.

In the interim, please do not hesitate to reach out to your CA Team should you wish to discuss these developments or share any insights regarding this Notice and/or Questionnaire (regulatory@cosmeticsalliance.ca).

New Personal Data Certificates for Companies Exporting to China

New Chinese Requirement for Personal Information:

It has come to our attention that the New Cosmetic Regulations in China (promulgated January 1, 2021) includes a provision requiring certain parties to provide "**personal certificates**" to

support the registration of products for sale in the Chinese marketplace. Specifically, we understand that the "personal certificates" expected to be filed include the passport numbers and/or driver's license numbers for the person(s) in charge of operations (legal representative) and the person(s) in charge of quality and safety. We understand that these provisions apply to personnel in BOTH domestic enterprises (i.e., in China) and "overseas production enterprises" (for products manufactured outside of China). These new requirements are set out in Article 10, with specific requirements outlined under the Registration Forms included under Annexes 4 and 6 of the New Cosmetic Regulations in China (excerpt from unofficial English translation; highlighted emphasis added). This information will be entered into and stored in the electronic Chinese Registration Portal when products are registered with the Chinese authorities.

Background Negotiations:

During the development of these new regulations in China, when it became clear that these "personal certificates" referenced under Article 10 related to personal identification documents such as passports and/or driver's license; we understand that negotiating parties strongly objected to the inclusion of such personal information, as it was unclear as to the intent and/or underlying need for such information to substantiate product registration. No where in the world is such information required to be filed for this type of regulatory application. In response to these objections, the Chinese authority is apparently insisting on this information as a means to ensure that the key individuals identified in any given registration are representative of 'real' and/or 'life' people with proof of identification. We understand that many attempts were undertaken to reverse the imposition of this specific requirement, including objections filed with the World Trade Organization (WTO) as a potential barrier to trade, given the precedent that this would establish. Unfortunately, these negotiations were unsuccessful to change the direction of the requirement.

Understandable Concerns with Requirement:

The type of information we understand are expected to be acceptable as "personal certificates" comprises extremely sensitive, personal information. Moreover, in this day in age, with this type of information being stored in digital forms, it is understandable, how one would not want to release such information very readily. In fact, digital security/vigilance training would strongly advise against providing such information, or at a minimum, to take great care in doing so. If such information is to be released, one should always look to confirm the corresponding information retention policy, as well as to receive some assurances to ensure an active, up-to-date privacy policy is available that outlines how such information is used, stored, deleted, and/or released; such that in any such transaction, the responsibilities of the receiving party are clear, in respect to any risk(s) to the parties providing the personal information.

At this juncture, regretfully, the new regulations in China are what they are… and correspondingly, members and businesses need to be aware of these new requirements. To address/mitigate some of these concerns, we outline some recommendations below as to how

these provisions may be addressed, while maintaining some degree of security related to the personal information in question.

Recommendations For Providing Information When Asked:

As this is a new regulatory requirement, your customers, vendors, partners may be asking for you to submit one or more "personal certificates" as proof of identification, for input into the Chinese Electronic Registration Portal. In responding to any such request, we would suggest that it is prudent to contemplate any or all of the following:

1. Ask for the underlying rationale (in writing) as to why this information is being sought, and how this information is to be used and how it will be protected (including by the Chinese authority).
2. Insist on seeing an active/current privacy policy regarding how this information will be used, stored, deleted and/or released. You may wish to insist on establishing some limits for data retention (i.e., how long is it reasonable for this information to be held).
3. Clarify expectations as to what you may need to do to facilitate the withdrawal and/or destruction of such information should you so choose to pursue such action.
4. Recognize that it is reasonable for you to clarify such policies for anyone whom you are sharing this information with (i.e., customers, vendors, partners, etc.) as well as the Chinese regulator. We understand that the Chinese regulator has provided standard operating protocols to their staff as to how to handle this information (however, to our understanding, this information is not readily distributed). We would strongly recommend that you get something in writing that acknowledges any such protections that may be in place.
5. As we understand it, only **one** certificate is needed/identified individual. It must be a valid, government issued, identification document. However, to our knowledge, there is nothing in the regulatory provision to insist that this document needs to be a passport. Therefore, proceeding with a driver's license number instead of a passport number, may be the most innocuous option to consider.

Lastly, and most importantly….

1. **Based on discussions with our colleagues from Cosmetics Europe (whom have been closest to and directly involved in these negotiations); we understand that in recognition of the sensitivities around this information, the Chinese authority MAY be willing to accept "hiding up to 5 digits (i.e., ##### or XXXXX) of the certificate reference.**

   Note: At this juncture, this course of action has not yet been officially confirmed in policy by the Chinese authority, however, we understand that in practice, it is being pursued by stakeholders. Furthermore, this option has only apparently been successfully pursued for passport numbers (although the underlying rationale should apply, irrespective of the

document in question). It is also not clear which 5 digits can be protected; or which would be the most appropriate to 'hide' to maximize security.

What CA Canada is Doing in the Interim:

Having just become aware of the specificity of these requirements, and the understandable concern with these provisions; CA Canada is already in the process of reaching out to Global Affairs Canada to explore options for raising concerns with the Chinese authorities. At a minimum, we will be looking to help identify any corresponding policy documents that could address any of the base concerns, as we have outlined in this update.

Please do not hesitate to touch base with our CA Team to discuss these developments further should you have any concerns. We would also strongly advise that you consult with legal counsel to discuss any concerns regarding such privacy considerations.

We will continue to monitor these developments and will update members as new information becomes available. In the interim, please inform us of any related experiences that you may have regarding these developments.

DEL Bulletin LEPP No. 116 Canada and European Union - Recognition of Good Manufacturing Practices Extra-Jurisdictional Inspection Outcomes

On April 22, 2021, Health Canada communicated in DEL Bulletin No. 111 that Canada and the European Union (EU) would officially recognize Good Manufacturing Practices (GMP) inspections conducted outside of their respective jurisdictions (i.e. extra-jurisdictional inspections). The scope was limited to extra-jurisdictional inspections conducted on or after April 1, 2021.

As a reminder and previously communicated to members on April 27th, 2021, prior to April 1st, 2021, a GMP Certificate of Compliance (CoC) issued by Health Canada or an MRA country for an inspection conducted outside of their respective jurisdictions was considered insufficient evidence to support a foreign site listed or to-be listed on a Drug Establishment Licence (DEL). Stakeholders were required to submit a copy of the CoC along with the full inspection report.

Health Canada is pleased to inform you that starting on July 12, 2021, Canada and the EU will also recognize extra-jurisdictional inspections conducted prior to April 1, 2021 as long as the Certificate of GMP Compliance (CoC) is within the period of validity issued by the EU Regulatory Authority. If the CoC is still valid, you may submit a DEL Application (FRM-0033) and a cover letter to Health Canada at hc.el.applications-le.sc@canada.ca. Health Canada will obtain the CoC from the EU on your behalf to support adding, amending or renewing the foreign building on your DEL once the application to add, amend or renew your DEL is filed.

IFRA IL1121 Updated text Guidance for the use of the IFRA Standards on traces of prohibited materials

IFRA recently updated the text guidance for the use of the IFRA Standards on traces of prohibited materials. The IFRA Risk Management Task Force updated the text on traces of materials prohibited by an IFRA Standard to reflect more recent scientific understanding and regulatory developments. Please find below the updated text standard guidance and the updated IFRA Standard Guidance.

Updated Text Standard Guidance

Updated IFRA Standard Guidance Prohibited Substances

https://www.cosmeticsalliance.ca/ifra-il1121-updated-text-guidance-for-the-use-of-the-ifra-standards-on-traces-of-prohibited-materials/

Drug Submission Performance Quarterly Reports (January-March 2021) and Annual Reports for TPD, BRDD & NNHPD

The Drug Submission Review Performance Reports provide detailed metrics about the timeliness of the pre-market drug review process against performance service standards. The quarterly report compares five consecutive quarters from January-March 2020 to January-March 2021. The annual report compares five consecutive fiscal years from 2016-2017 to 2020-2021. The reports are broken down by operational areas. The Therapeutic Product Directorate (TPD) report summarises performance metrics for pharmaceuticals. The Biologic and Radiopharmaceutical Drugs Directorate (BRDD) report summarises performance metrics for biologics. The Natural and Non-Prescription Health Products Directorate (NNHPD) report summarises performance metrics for non-prescription (over-the-counter) and disinfectant drugs.

Quarterly Reports important highlights:

NNHPD:

- There was a significant increase in the volume of Drug Identification Number Applications for Disinfectant products (DIND) received.
- There was a 55% decrease in the number of DINA submissions received in Q2 2020-2021 (26) compared to Q1 2020-2021 (58), a 96% increase when comparing Q3 2020-2021 (51) to Q2 2020-2021 and a 47% decrease when comparing Q4 2020-2021 (27) to Q2 2020-2021.
- There was a 3% increase in the number of DINF submissions received in Q2 2020-2021 (80) compared to Q1 2020-2021 (78), a 50% decrease when comparing Q3 2020-2021 (40) to Q2 2020-2021 and a 22.5% decrease when comparing Q4 2020-2021 (31) to Q3 2020-2021.

TPD – EN/FR

BRRD – EN/ FR

NNHPD – EN/FR

Annual Reports Important Highlights:

- A performance standard of 99.99% was achieved for DIN-D submissions with 1/214 submissions completed after the target date. A performance standard of 98% was achieved for DINA submissions with 1/75 submissions cleared after the target date. A performance target of 80% was achieved for ANDS submissions with 1/5 submission completed after the target date.
- NDED achieved a performance standard of 99.99% for cost recovered submissions with 3/876 submissions completed after the target dates.
- A performance standard of 81% was achieved for disinfectant related PDC submissions with 23/120 submissions completed after the target date and a performance standard of 98% was achieved for OTC s.
- NDED achieved a performance standard of 99.95% was achieved for non-cost recovered submissions with 28/535 submissions completed after the target date.

TPD – EN/FR

BRRD – EN/FR

NNHPD – EN/FR

Future of Supply Chains survey from the Conference Board of Canada

The Conference Board of Canada is inviting organizations to participate in a survey to better understand how and why businesses are changing the ways they source inputs within their supply chains. In partnership with The Conference Board Inc., the results will allow the two organizations to share insights on the similarities and differences in global supply chain practices in Canada, the U.S., and Europe.

The survey takes 10-15 minutes to complete and closes July 23, 2021. If you have any questions, please contact Swapna Nair, Senior Economist, Global Commerce Centre, The Conference Board of Canada, nair@conferenceboard.ca.

Click on the links below to participate:

The Future of Supply Chains: How Are They Changing?
L'avenir des chaînes d'approvisionnement : Comment évoluent-elles ?

Final Report Release: Strengthening Governance of the Antimicrobial Resistance Response Across One Health in Canada

On July 15, the Strengthening Governance o the Antimicrobial Resistance Response Across One Health was released. This report is the result of a request by the Public Health Agency of Canada (PHAC) to develop feasible, credible, and sustainable governance model options to strengthen the Antimicrobial Resistance (AMR) response in Canada across One Health, without recommending a preferred option. Under the leadership of a steering committee comprised of Canadian AMR and policy experts from across One Health the project undertook extensive consultation and completed a thorough literature review. Below is the link to the final report and supplemental documents.

Volume I: Final Report
Volume II: Supplemental Documents

Environmental Updates

Publication of the final Screening Assessment and the Risk Management Approach for the Anthraquinones Group

The Final Screening Assessment for the Anthraquinones Group was published. The Proposed Risk Management Approach for Solvent Violet 13 was also published for a 60-day public comment period ending on September 15, 2021.These 7 substances were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns.

Substances in the Anthraquinones Group

CAS RN[a]	Domestic Substances List name	Common name
81-48-1	9,10-Anthracenedione, 1-hydroxy-4-[(4- methylphenyl)amino]-	Solvent Violet 13
81-77-6	5,9,14,18-Anthrazinetetrone, 6,15-dihydro-	Pigment Blue 60
6408-72-6	9,10-Anthracenedione, 1,4-diamino-2,3- diphenoxy-	Solvent Violet 59
14233-37-5	9,10-Anthracenedione, 1,4-bis[(1-methylethyl)amino]-	Solvent Blue 36
17418-58-5	9,10-Anthracenedione, 1-amino-4- hydroxy-2-phenoxy-	Disperse Red 60
72391-24-3	Benzenesulfonic acid, [[(chloroacetyl)amino]methyl][4-[[4- (cyclohexylamino)-9,10-dihydro-9,10- dioxo-1- anthracenyl]amino]phenoxy]methyl-, monosodium salt	Acid Blue 239
74499-36-8[b, c]	9,10-Anthracenedione, 1,4-diamino-,N,N′-mixed 2-ethylhexyl and Me and pentyl derivs.	NA

The other 8 substances were determined to be of low concern through other approaches, and decisions for these substances are provided in separate reports (CAS RNs 2379-79-5, 15791-78-3, 19720-45-7, 28173-59-3, 2475-45-8, 4051-63-2, 13676-91-0 and 19286-75-0). It is concluded that the substance Solvent Violet 13 may be harmful to human health and meets the criteria under section 64(c) of the Canadian Environmental Protection Act, 1999 (CEPA). A risk management approach has been published concurrently to outline the proposed risk management actions.

- Final Screening Assessment
- Risk Management Approach
- *Canada Gazette* Notice

Post-Consumer Waste Updates

Recent Changes to Producer Responsibility Organizations (PRO)

Please note there are now two Producer Responsibility Organizations (PRO) in Ontario – Green For Life (GFL) has acquired Resource Recovery Alliance (RRA) and Canadian Stewardship Alliance (CSA) and Retail Council of Canada (RCC) is now PRO too.

Producers are required to register with RPRA, confirming your company is a producer and the materials supplied into Ontario. Only PROs that registered with RPRA between Aug. 1 and Nov. 1 can continue to sign representation agreements with producers. This is now a competitive marketplace in Ontario and Cosmetics Alliance will not endorse any of the two PROs and we encourage members to do their research when picking a PRO.

New Webinar: "GFL Introduces RRA"

Date: Thursday, July 22, 2021

Time: 1:00 p.m., Eastern Time

Register

Green For Life (GFL) Environmental is pleased to introduce Resource Recovery Alliance (RRA) PRO!

Join the webinar: Register now to learn more about RRA and our **Promise to Producers.**

GFL is pleased to invite producers to meet its **newly formed subsidiary, RRA**, and learn how RRA intends to ensure your full compliance to **Ontario's new Blue Box Regulation**.

The Blue Box Regulation was released on June 3, 2021, ushering in a new wave of extended producer responsibility (EPR) in Canada for packaging and paper products.

As Canadians grow increasingly concerned about environmental issues and expect more from government and business, a failing grade on recycling and environmental outcomes can be detrimental to Ontario's major brands.

RRA PRO customers can rely on 10+ years of trusted compliance expertise across Canada, guaranteed data confidentiality, and much more.

Join the webinar to learn about:

- Your new obligations and how RRA will ensure you meet them
- The many benefits of signing with RRA

- New Representation Agreement
- Q&A

Blue Box Trade Associations Working Group Meeting Materials

On July 14, the Blue Box Trade Association Working Group held a meeting on Blue Box. Below are the meeting notes and facilitation deck.

CBA Blue Box Trade Association Deck

Overview of GFL's Acquisition of CSSA