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Re: Cosmetics Alliance (CA) Canada Input on Pre-Consultation Notice to Amend the *Cosmetic Regulations* Published July 16, 2021

EXECUTIVE SUMMARY

Cosmetics Alliance (CA) Canada welcomes the opportunity for early engagement on the Pre-Consultation Notice that Health Canada published regarding possible amendments to the *Cosmetic Regulations* in Canada. To support these efforts, we outline support in principle for the proposal to enable the disclosure of certain contact allergen(s) on labels; including the need for such regulatory modernization reforms to re-imagine how labels are construed in the 21st century to harness the power and potential of digital solutions. However, we also present a number of suggestions and recommendations to help clarify and hone the scope of these proposals, to ensure that they are 'right-sized', practical, and in line with international precedents, so to avoid any disruptions or inadvertent barriers to trade.

As for the proposed operational amendments as outlined, we present a number of questions to further elucidate the underlying rationale for the proposals and to seek greater clarity and understanding as to the net objective(s) or the specific regulatory challenges that these proposed amendments are intending to address. Although we appreciate the efforts to consider operational improvements, in the absence of further background context, it is difficult to meaningfully engage with more constructive feedback at this time. For these operational oversight proposals, we suggest that further dialogue is needed in order to more clearly elucidate the intended purpose so that additional input can be provided.

Finally, and perhaps most importantly, we note that many of the considerations outlined in this Pre-Consultation mirror consultations that are already currently underway in relation to the Self-Care Framework (SCF). We note that this Notice makes no reference to these important regulatory reforms, with which cosmetic and personal care products are an integral part. Regretfully, this is a significant missed opportunity for collaboration and coordination, and

we urge Health Canada to ensure that these proposals be considered within the context of the broader modernization reforms that will ultimately be enabled under the SCF. It is critical that any reforms to the *Cosmetic Regulations* look to shape, as appropriate, or are aligned in principle and practice to those that are also being established for similar, low-risk, self-care products.

Given the early nature of this Pre-Consultation, we welcome further opportunity to discuss this preliminary feedback and input with officials, as Health Canada looks to refine these proposals, moving forward.

INTRODUCTION

Cosmetics Alliance (CA) Canada appreciates the opportunity to provide early input for consideration as Health Canada contemplates possible amendments to the Canadian *Cosmetic Regulations*. As outlined in the above-referenced Pre-Consultation Notice (the "Notice"), we understand that the primary objective of the proposed amendments is to enable enhanced disclosure and labelling provisions to *"… inform consumers about the presence of specific fragrance allergens in cosmetics…"*, including the possibility of enabling the digitization of specific labelling requirements, given the technological evolutions now commonplace in today's modern society. We also understand that the proposed amendments also look to clarify certain definitional elements, in addition to proposing enhanced reporting and enforcement measures, intended to facilitate and enhance operational oversight. Notionally, although CA Canada is largely supportive of the base principles underpinning the regulatory amendments outlined in the Notice, we respectfully note that this proposal does not appear to consider or contextualize in any way, the important reforms presently being pursued under the Self-Care Framework (SCF) which implicitly implicates 'low-risk' cosmetics and personal care products. In this regard, this pre-consultation regretfully fails to recognize the holistic regulatory modernization and streamlining efforts that are seeking to build efficiencies and broader alignment and consistency with regards to how 'low-risk' health products (including cosmetics) are regulated in Canada. This represents a significant missed opportunity that CA Canada would encourage Health Canada officials to further explore, as these regulatory proposals move through the next phase(s) of consultations.

To facilitate review and consideration of CA Canada's early input regarding this Notice, we have organized our commentary into the following three Sections:

1. Making the connection with the Self-Care Framework (SCF) as a foundational underpinning to any corresponding regulatory modernization efforts regarding cosmetics and personal care products;
2. Specific technical input regarding the labelling, operational and administrative proposals*; and
3. Overview of potential additional considerations that could ultimately enable key coordination reforms related to SCF modernization.

* Under Section 2 (Specific Technical Input), observations grouped under the **'GREEN'** sub-section headings, highlight important connections to the SCF that we believe need to be considered as these proposals are refined moving forward.

CA Canada acknowledges the corresponding Pre-Consultation Questionnaire (the "Questionnaire") made available in conjunction with this Notice; however, given the broader, holistic approach that we are taking with our commentary, we have elected to submit our feedback independently of this prescribed format.

Finally, CA Canada is fully aware and supportive of the corresponding submissions as filed by the US Personal Care Products Council (US PCPC) as well as the US Fragrance Creators Association (US FCA). The technical considerations, particularly in relation to the allergen(s) proposals provide critical supporting perspectives that we believe mirror many of the underlying observations presented herein. We are also aware of representations submitted by other Trade Associations with interests in these developments. Finally, we understand that some of our members may engage directly with similar commentary of their own.

SECTION 1 – MAKING THE CONNECTION WITH THE SELF-CARE FRAMEMORK (CHPSD'S MISSED OPPORTUNITY): NEED FOR COLLABORATION AND COORDINATION

As the Consumer and Hazardous Products Safety Directorate (CHPSD) is no doubt aware, for the past several years, significant efforts have been underway to modernize how cosmetic, personal care and other low-risk health products are regulated in Canada, to ensure that like products have similar regulatory oversight, despite differential regulatory classifications (i.e., cosmetics, drugs, or natural health products). These modernization reforms look to build a more consistent, effective, and efficient regulatory approach that will serve to level the playing field and rectify the long-standing discrepancies that presently exist with today's regulatory construct.

For example, similar products such as toothpastes, shampoos, or sunscreen products can today be regulated under three different sets of regulations with vastly different regulatory obligations, simply based on claims or origins of ingredients, despite representing similar low-risk profiles. Over the years, this reality has led to a patch work of regulatory policies that have resulted in a fragmented oversight landscape that has seen the application of regulatory considerations designed and intended for higher risk drug products (e.g., oncology medication) being applied to lower risk health products intended for self-care maintenance, with little to no benefit (e.g., drug shortages reporting). This significant disparity also extends to regulatory enforcement powers, such that similar products can be subject to significant different authorities or penalties (e.g., recall provisions), based solely on their regulatory classification as illustrated by Health Canada officials during the Health Products and Food Branch Fall Strategic Planning Multistakeholder Consultation (September 2017) and re-affirmed many times since, including at several CA Canada Regulatory Workshops.

Figure 1: Building the case for Self-Care Reforms (excerpt from Health Canada Presentations by then Deputy Minister Simon Kennedy, September 2017)

Similar products…			
These three toothpastes are sold side by side on store shelves	**Cosmetic…**  **…does not have a therapeutic claim**	**Natural Health Product…**  **…has a therapeutic claim and natural ingredient**	**Non-prescription Drug…**  **…has a therapeutic claim and synthetic ingredients**
…different rules			
Different rules	• No product review • No site licence • No inspection • No cost to industry • No adverse reaction reporting	• Expedited product review based on claims • Site licence • No inspection • No cost to industry • Adverse reaction reporting	• In-depth product review based on scientific evidence • Establishment licence • Mandatory inspections • Cost to industry (up to $340,000) • Adverse reaction reporting
Inconsistent powers	• No recall authorities • Maximum fine is $5,000	• No recall authorities • Maximum fine is $5,000	• Recall authorities exist • Maximum fine is $5,000,000

HPFB Presentation – HPFB Fall Strategic Planning Multistakeholder Consultation (Sept. 2017)

Overall, this regulatory disparity is highly inefficient, ineffectively ties up resources in regulatory constraints that add little to no value to any stakeholder, including Health Canada's own officials, and simply makes little sense in terms of sound regulatory policy.

WHY THIS HISTORICAL OVERVIEW IS IMPORTANT IN THE CONTEXT OF THIS PROPOSAL

CA Canada recognizes that the SCF is largely being led by the Non-Prescription and Natural Health Products Directorate (NNHPD) under the Health Products and Foods Branch (HPFB). However, the cadre of low-risk products implicated by the SCF clearly extends to cosmetics and personal care products presently regulated by the CHPSD under the Healthy Environments and Consumer Safety Branch (HECS). Therefore, any proposal to amend the *Cosmetic Regulations* should be seen and presented as an important opportunity to build consistency in approaches and enable the long-standing reforms and leveling of the 'regulatory playing field' that the SCF is ultimately intending to resolve. In fact, the importance of this connection was one of the key highlights of the international joint symposium recently hosted by CA Canada and Health Canada

in 2019, held in conjunction with the 14th Annual Meeting of the International Cooperation for Cosmetic Regulations (ICCR-14) in Montreal.

DUPLICATION OF EFFORTS AND NEED FOR BETTER COORDINATION AND ALIGNMENT MOVING FORWARD

To the members of CA Canada as well as other stakeholders, the overarching observation of this pre-consultation process is the absence of any acknowledgement of Health Canada's SCF in the Notice. Further, there appears to have been no coordination of the proposals outlined in the Notice between the CHPSD and the NNHPD who is Health Canada's lead on the SCF, who regulate similar low-risk products, and who is also conducting related consultations on similar proposals at this very same time.

This absence of coordination and alignment of purpose only serves to undermine the commitment of CHPSD to this important regulatory modernization by Health Canada which the SCF is intended to achieve. In practical terms, this failure to coordinate means that Health Canada is holding two duplicitous consultations on many of the essentially same matters – such as allergen labelling – as these concepts apply equally to products regulated not just by the *Cosmetic Regulations* but also by the *Drug* and *Natural Health Product Regulations*. The fact that these latter regulations are administered by a different Directorate, in a different branch of Health Canada, should NOT justify the lack of coordination or unnecessary duplicitous use of everyone's time and resources including Health Canada staff. We trust that senior Health Canada administrators would be horrified to learn that their department has such an abundance of resources that they would hold the essentially same consultations twice for lack of coordination!

Additionally, and perhaps even more concerning, this failure to grasp the full benefits of the SCF and its objective of aligning the regulation of like products has been lost. In addition to allergen labeling, other important matters such as digital labelling generally, and its application for "small" packaging, does not appear to be coordinated between the two consultations now underway. Coordination could have ensured that all of these like matters be considered together to provide the aligned approach necessary for the SCF. If anything, it just furthers the continuation of the siloed regulation of these products which the SCF is intended to resolve.

We would respectfully note that the SCF and its' modernization of the regulation of all self-care products – cosmetics, natural health products, and non-prescription drugs – is not only the stated policy objective of Health Canada but has been or is currently being implemented through Health Canada's forward regulatory plan, trade agreements, and administrative measures. In this regard, we should all remember the presentation by then Deputy Minister, Simon Kennedy, in 2017 committing Health Canada to the SCF and the Health Canada slide used to point out the absurdity of regulating common products such as toothpaste under three differing regulations, as illustrated above under Figure 1.

We would also point out that with the Canada-United States-Mexico Agreement (CUSMA), the Government of Canada specifically recognized products that can be both a "cosmetic" and a "non-prescription drug" or "natural health product". Through the requirements of the agreement which

were implemented as of July 1st, 2020, Health Canada confirmed its' commitment to a key principle of the SCF that products of like safety/risk profiles should be treated alike:

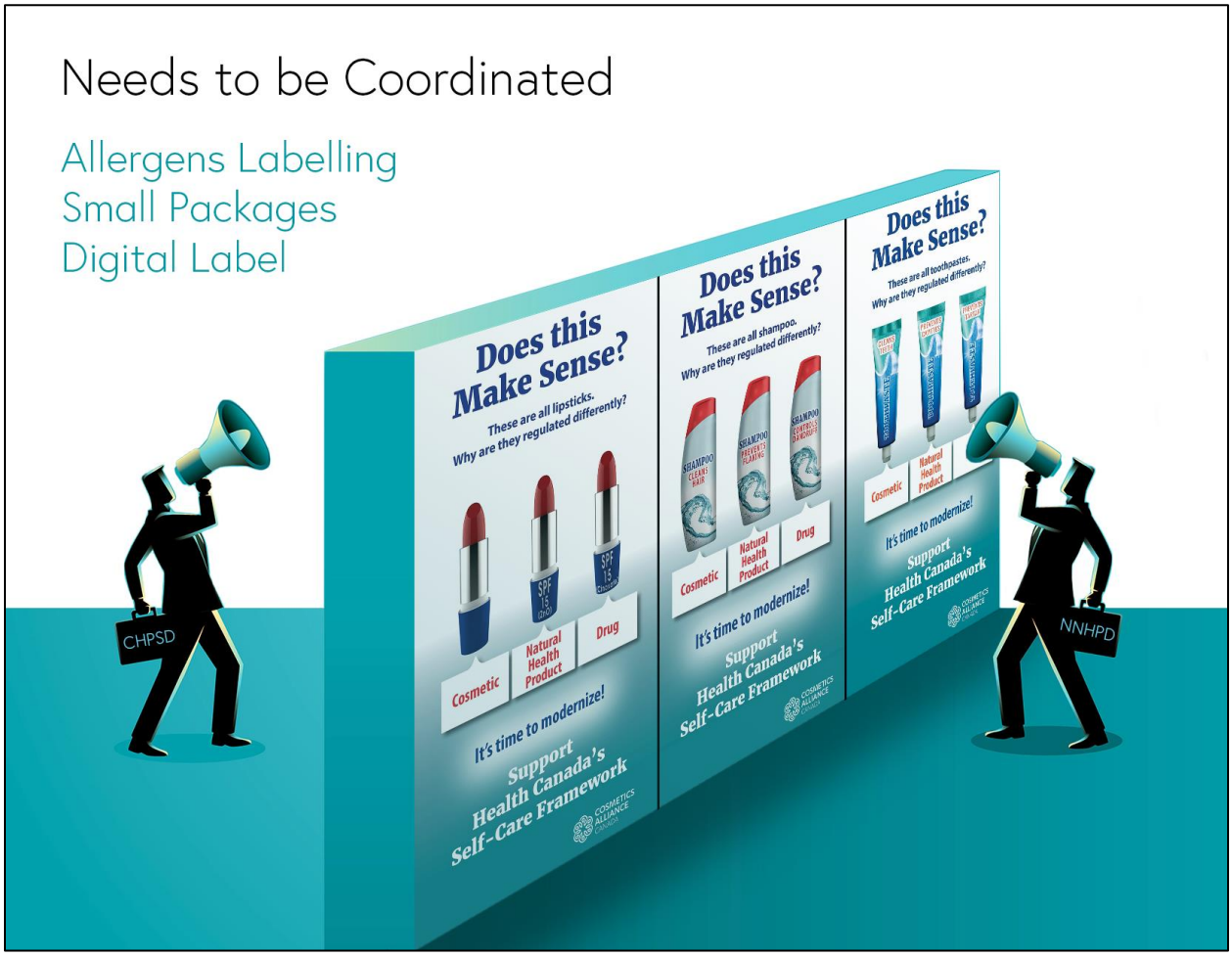
> ***Appendix 1 o ANNEX 12-B – Cosmetic Products***
>
> *2. This Appendix applies to toothpastes, mouthwashes, personal care use antiseptic skin cleansers, sunscreens, anti-dandruff shampoos, diaper-rash creams, antiperspirants, medicated skin care products, [Footnote 5] and acne products as set out in the following subparagraphs:*
>
> - *(a) for Canada, products that:*
>   - *(i) are for topical use in the oral cavity or on unbroken skin that act in a localized and non-systemic manner;*
>   - *(ii) are authorized for sale in Canada;*
>   - *(iii) are a non-prescription drug product or a natural health product; and*
>   - *(iv) meet the definition of a "cosmetic" in section 2 of the Food and Drugs Act, R.S.C., 1985, c.F-27, as amended;*
>
> *5. The Parties shall endeavor to strengthen their cooperation in the regulation of products covered by paragraph 2.*

If Canadian and U.S regulators are required by Section 5 to *"… strengthen their cooperation…"* in the regulation of these products, then how can this occur if CHPSD and NNHPD – both within Health Canada - are not also coordinating their modernization efforts as this current set of consultations appear to demonstrate?

Surely it is time to move beyond these administrative siloes and for the two Health Canada Directorates responsible for self-care products to actively breakdown the wall between two departments, as illustrated in Figure 2, and look to coordinate and align these respective efforts! In light of these observations, we recommend that no further steps be taken by CHPSD to finalize or implement any of these regulatory proposals until such time as they have been reviewed under the lens of the Self-Care Framework to ensure a common, consistent alignment in their application to all similar self-care products, moving forward.

Our detailed comments on the specific matters being considered are included in the sections which follow and will be again emphasized and presented in the similar consultation being now being undertaken by NNHPD.

Figure 2: Understanding the Overlap Between this Pre-Notice and On-Going Consultations under the SCF – Illustrating Why Better Coordination is Needed to Enable the SCF Modernization Efforts



SECTION 2 – TECHNICAL COMMENTARY REGARDING SPECIFIC PROPOSALS

Under this Section, we provide specific technical considerations in relation to each of the specific proposals as identified in the Notice. We have included input related to certain core elements covered under the Questionnaire, where relevant. Finally, in the spirit of the commentary we outline under Section 1, above, wherever possible, we point to key alignment considerations and important connections to the SCF, to promote greater alignment in core principles, as appropriate.

DISCLOSURE OF SPECIFIC ALLERGEN(S) ON COSMETIC LABELS: PROPOSAL 1

DECLARATION OF SPECIFIC "FRAGRANCE ALLERGEN(S)"

CA Canada understands that CHPSD is contemplating adding a provision to require the disclosure of specific "fragrance allergens" on cosmetic labels in line with current practices in Europe (under the European Commission's (EC) Cosmetic Regulations). Firstly, we would note that the allergen(s) in question are all contact allergens. We also strongly object to the characterization of these allergens as "fragrance" allergens, as many of these allergen(s) are constituents within botanical ingredients and can therefore be introduced into products through more than just fragrances. Correspondingly, this characterization is misleading and inappropriate. Given these observations, we would suggest this proposal be re-framed to reflect specific contact allergen(s), with the onus on "fragrance" removed. We would note that this generic approach is consistent with how these allergen(s) are referenced in the European context.

Further to many past discussions with Health Canada officials, CHPSD is well aware that CA Canada supports the base premise that disclosure of ingredients, including allergens on label may provide consumers with relevant information that could facilitate secondary allergy prevention and self-selection of products to which they would not be potentially allergic to. Therefore, although we support the underlying principle behind this proposal, there are a number of key imperatives that we would urge officials to consider when developing the underlying 'details', as elaborated on below.

REFINING THE WHAT – ENSURING PRACTICAL ALIGNMENT WITH ESTABLISHED REGULATORY PRECEDENT

Regulatory convergence is a key imperative for CA Canada, and as such, we support any initiatives that look to build greater consistency in regulatory considerations and to facilitate global trade. Based on our review of the pre-consultation proposals as presented, we do have some significant concerns with the apparent scope as reflected under Appendix 1 of the Notice.

This Appendix appears to focus on the expanded list of 87 potential contact allergens as reflected in the 2012 Opinion by the Scientific Committee on Consumer Safety (SCCS), as cited and which is currently the subject of a DRAFT proposed amendment to the European Regulation. We understand that this draft remains under development, discussion and advisement since 2014, and has not yet been finalized. Correspondingly, this proposed amendment in Europe continues to be the subject of significant scientific scrutiny and dialogue; and with relevent details still emerging, may be subject to substantial change prior to final adoption.

On this basis, the present scope of the proposal as outlined by CHPSD is out of step with current practice in Europe, and as such may not be practically aligned with the established regulatory precedent.

On the basis of the above, CA Canada would suggest that the Scope of these proposals for contact allergen(s) disclosure be refined to be in line with practices currently in place in Europe; specifically:

- Disclosure of the 26 (now 25[1]) recognized contact allergens (when concentrations are greater than 0.001% in leave-on cosmetic products and greater than 0.01% in rinse-off products) as presently reflected under Annex III of the EU Cosmetics Regulation No. 1223/2009).
- This early limitation in scope is imperative to ultimately allow for meaningful resolution of some of the technical considerations we understand are still in question regarding the DRAFT revised Annex III amendments, including important clarifications regarding, risk characterization, identification and nomenclature of potentially implicated ingredients; analytical methods; the need for further evolution in relevant patch testing panels to accommodate a more extensive list of allergens that consumers could relate to for secondary prevention purposes; etc.
- Taking this approach at this time, we believe will ensure that these proposals are 'right-sized' and consistent with present day practice, and therefore, not represent an impediment to trade.

Furthermore:

- Extension of corresponding disclosure obligations to the expanded list of 61 additional potential allergens (i.e., totalling 87 contact allergens) presently under discussion in Europe is pre-mature and would not be appropriate until such time that these considerations are resolved and affirmed in practice in the Europe context (given the technical consultations that underpin these proposed evolutions in approach are all centered in Europe).
- Although we acknowledge, by the time that this proposed amendment comes into force, it is possible that the corresponding provisions in Europe will be finalized and adopted. However, practically speaking, we understand that transitional considerations will be built into the process in Europe, to enable the market to come into compliance over the course of several years following the formalization of any revised Annex. In this regard, we believe that it would be inappropriate for any corresponding amendments in Canada to pre-empt implementation in the European context. Alternatively, if finalization of the draft Annex in Europe is resolved in the relative short-term, it may be more efficient simply to wait until implementation of these measures are practically in Europe to allow for broader alignment sooner, rather than later.
- As for transitional considerations, we would encourage Health Canada to transparently build into any amendment, practical transition timelines in line with similar precedents such as what we understand is presently being considered in

[1] One ingredient (lyral, or "HICC") has since been added to EU Annex II and is prohibited (August 2021). At present, a similar prohibition/restriction is not yet in place in the Canadian context, and therefore, the proposed "contact allergens" as referenced would extend to 26 ingredients at this time.

the European context (i.e., 3 years after coming into force for manufacturing/production with an addition 2 years to accommodate for sell-through at the market level).

ELABORATING ON WHY? – PROMOTING GREATER TRANSPARENCY WITH NET REGULATORY OBJECTIVE

In refining the scope of this proposal, CA Canada would urge Health Canada to reflect on the intended regulatory objective(s) behind these proposals, so to ensure an appropriately 'right-sized' approach. This exercise should not be simply about the adoption of 'lists' from abroad, but rather should be more circumspect and deliberate, to ensure that the proposed disclosure elements would in fact deliver on the intended regulatory objective(s).

Case in point, given the principled objectives of supporting secondary allergy prevention and consumer self-selection that we elaborate on above, any mitigation tool developed needs to be relatable to the consumer. In other words, to be effective, the consumer needs to be able to readily identify with the contact allergen in question, in order to enable product self-selection. To facilitate this, appropriate patch testing panels need first to be available that cover the full spectrum of confirmed 'contact allergens' for which disclosure is directed. In the absence of such innovations, the corresponding disclosure information would be meaningless and certainly would not enable the desired regulatory outcome. Otherwise, a consumer may simply choose to avoid fragrances, flavours, or botanical ingredients altogether, which can simply be facilitated through information already mandated to be generically disclosed on label. We believe this observation illustrates why it is critical to ensure that the scope of any corresponding proposals be appropriately defined.

Therefore, in the interest of promoting greater transparency and facilitating future stakeholder engagement with this proposal, we would strongly recommend that Health Canada further elaborate on the net intent and most importantly clarify the net regulatory objective(s) that these interventions are looking to achieve. These details, we believe, will prove to be very helpful in supporting a more thorough cost-benefit analysis, and promote a more constructive and effective consultation dialogue, moving forward.

POSSIBLE INSIGHTS ON HOW? – FACILITATING A MODERNIZED APPROACH THAT WILL ENABLE CONSUMER CHOICE OVER TIME

Any regulatory proposals that potentially impacts the amount of information to be included on a product label needs to be carefully scrutinized, as 'label real estate' (i.e., the amount of room available to accommodate text on label) will always be at a premium. In today's marketplace, where minimizing packaging and reducing the environmental footprint of products are important priorities for all stakeholders, including the Government of Canada's 'net zero' commitments, establishing labelling solutions that do not inadvertently lead to increased packaging size (to accommodate mandated 'on-pack' information) should be a key consideration of any corresponding proposals. On this basis, CA Canada appreciates that this Notice looks to explore how digital technology can be leveraged to support a modernized approach to the proposed

labelling objective as outlined. We will elaborate further on these important considerations under *"Digital Labelling Considerations"*, below.

In addition to digital labelling considerations, we would also suggest that it is important for labelling disclosure proposals such as those outlined in the Notice to provide for sufficient flexibility to accommodate the identification of new 'contact allergens' over time. As science evolves, so should these provisions. How this can be effectively managed should be proactively discussed, as these proposals are conceptualized. The digital labeling considerations as outlined may prove very helpful in this regard, as the ease to which evolving allergen(s) disclosure obligations may be accommodated through a digital solution we would suggest may offer significant opportunities in this regard.

Finally, we would stress that in refining these proposals, it is highly recommended that such contact allergen(s) be simply disclosed through incorporation on ingredient lists and not highlighting/listing them separately, be they presented 'on pack' or 'off pack'. This approach would be in line with how similar disclosure practices are implemented around the world and consistent with how consumers have grown used to looking for this type of information. Changing this common practice and how consumers today are most likely to readily relate to ingredient lists on cosmetic and personal care products, would require a significant re-education/outreach campaign, with little evidence of further additional benefit.

CONTACT ALLERGEN(S) LABELLING – MAKING THE CONNECTION WITH THE SELF-CARE FRAMEWORK

Any proposal regarding allergen(s) disclosure is inextricably linked to the allergen(s) labelling considerations currently under consultation in relation to the SCF. Although the present proposals as outlined under the Phase 1 consultations are largely focused on priority food allergens, we understand the original scope as proposed was only intended as a 'starting point', and that considerations for 'other allergens' are envisioned based on evolving discussions with certain stakeholders, including CA Canada.

In this regard, we have proactively been discussing with the SCF team how other allergens (such as contact allergen(s)) could/should be considered. We have proposed and would welcome a dialogue in this regard, and we would suggest, given the considerations outlined under this Notice, that these discussions should occur concurrently, such that whatever ultimately is developed in the context of cosmetics and personal care products should equally apply to all like products under the SCF. Taking the opportunity at this juncture to address how these proposals can be brought together into a single, cohesive, and aligned approach we believe will provide for effective resolution and coordination of these efforts in a manner that is fully in line with the overall intent of the SCF. We trust CHPSD would concur that it would make no sense to have a unique solution exclusive to cosmetics, when the same contact allergen(s) may also be found across all low-risk, topical self-care product categories.

DIGITAL LABELLING CONSIDERATIONS

CA Canada fully supports the proposal to explore opportunities to contemplate how to enable the disclosure of certain label elements (including contact allergen(s)) 'off pack' and onto a digital platform (i.e., digital label). These proposed considerations represent a timely and integral part of regulatory modernization efforts; particularly given the rapid evolution of e-market channels and the increasing reality that more and more consumers are making purchase decisions and completing purchase transactions on-line, often without ever interfacing with the physical label, until after the product arrives at their doorstep. On this basis, we strongly believe that integration and recognition of digital labelling elements is the way of the future, with demand for product information to be available via digital means only continuing to grow.

As CHPSD contemplates these flexibilities, we would urge officials to look to regulatory amendments that will enable the digital label; leaving room for flexibilities and implementation details to be worked out in policy and guidance. In essence, we would strongly recommend that these proposals should lay the groundwork to allow for sponsors to have the flexibility to disclose specific contact allergen(s) information directly on product labels OR through some alternative vehicle, such as a digital label, with the *proviso* that should this information be moved 'off-pack', that it is critical that a consumer who interfaces directly with the package is easily directed to where/how to get access to this information, so to ensure consumers are able to access information at both the point of sale and the point of use.

For example, should these provisions enable such disclosures to be moved 'off pack', the label should clearly incorporate details reflecting considerations such as "For ingredient information – see 'insert where to get information'" OR "Contact 'toll-free consumer line'", as appropriate).

ENABLING THE DIGITAL LABEL – MAKING THE CONNECTION WITH THE SELF-CARE FRAMEWORK

Although we very much appreciate the integration of digital labelling elements in this Notice, these exact same considerations are an integral piece of the improved labelling consultations already initiated in support of the SCF. In fact, digital labelling considerations have already been implemented in practice for certain information related to drug facts table labelling, as a proof of principle for the development of similar measures. The underlying principles behind these specific measures we would submit are very much in line with those under consideration here, and as such may represent important guideposts for consideration moving forward.

So not to recreate 'the wheel', we strongly urge CHPSD to connect with the Self-Care Team at NNHPD and look to build these considerations in line with the collective pursuits that are already being shaped into the SCF. We implore Health Canada to avoid considering a 'cosmetic'-centric regulatory amendment in isolation that could potentially undermine the objectives of the SCF. When it comes to the enabling the digital label, we would once again insist that what makes sense for cosmetics/personal care products should equally apply to all low-risk, self-care product categories.

ENABLING FLEXIBILITY TO ALLOW FOR DISCLOSURE OF INGREDIENTS ON SMALL /ORNAMENTAL PACKAGES: PROPOSAL 2

Although CA Canada appreciates the details concerning small/ornamental packages as outlined in the Notice, further to the commentary above under 'Digital Labelling Considerations', any consideration for taking information 'off pack' should be predicated on ensuring that sufficient information/directions be available 'on-pack' in order to direct consumers to where to find the designated information. The present scope as presented in the Notice appears to suggest that flexibilities would only be considered for products intended to be sold in "small packaging". We believe that this proposal is largely predicated on the historical precedent (as currently reflected in regulation) wherein the physical product label is the primary interface for product labelling.

Although this approach might have been justified in the past, under a modernized framework, wherein the Regulation is looking to enable a product label that may now involve both 'on-pack' and 'off-pack' (i.e., digital) elements, we would stress that the regulatory paradigm has shifted, and therefore the corresponding policy elements should also similarly evolve. On this basis, we would suggest that it would be more appropriate for any flexibilities be equally applicable to all products, irrespective of packaging size.

ALIGNMENT WITH NHP LABELLING FLEXIBILITIES – MAKING THE CONNECTION WITH THE SELF-CARE FRAMEWORK

The simplified approach outlined above, where digital labelling flexibilities are not, predicated on specific packaging size, is an important consideration already being advanced in the context of the on-going SCF consultations. We would again urge CHPSD to look to the SCF dialogue to consider how to address these flexibilities and to take on the precedent that within the context of a modernized labelling framework, size restrictions need no longer to be an underlying determinant upon which to base the designation of any corresponding flexibilities.

OPERATIONAL OVERSIGHT CONSIDERATIONS: PROPOSALS 3 (A – H)

DEFINITIONS (ACTIVITIES) – MANUFACTURER/IMPORTER/DISTRIBUTOR

MANUFACTURER/IMPORTER/DISTRIBUTOR

Based on our review of the Notice, it is not at all clear as to why a change to these definitions is believed to be necessary. Before pursuing these proposals, CA Canada would urge Health Canada to more clearly delineate what oversight challenges this proposal is looking to resolve, and more importantly how it is envisioned that such definitional changes will enable enhanced or improved regulatory oversight. Providing a number of specific examples to help illustrate the circumstances that these considerations are looking to address would also be beneficial to further contextualize the proposal. These clarifications are critical to allow stakeholders to understand

the underlying perceptions that may be driving these proposals and how these might differ from the practical reality.

At this juncture, we are struggling with understanding what these clarifications in definitions are looking to accomplish from an operational or regulatory efficiencies perspective. In the absence of further rationale for these proposed changes, we would suggest that keeping with the status quo may be in order – If it isn't broken, no need to fix it.

RINSE-OFF VS LEAVE-ON

Notionally, CA Canada supports the integration of a regulatory definition that would provide greater predictability and transparency to enable the designation of a product as a rinse-off or leave-on product for notification purposes. However, we would also contend that there are some products that may not neatly fall into either category (e.g., certain oral care products, cleansing masks, etc.), therefore, we would suggest that considerations for other product type designations should also be contemplated. We also appreciate how the inclusion of this information in a Cosmetic Notification could support the proposed allergen(s) disclosure provisions.

In addition to the details outlined in the Notice, we would also encourage that further clarity be provided on specifically how these definitions might be applied for risk and safety assessment purposes and that the corresponding intent of such designations would not be for pre-screening purposes. This clarification is important to ensure that stakeholders clearly understand how this information will be used and interpreted moving forward.

CONSISTENCY IN DEFINITIONS – MAKING THE CONNECTION WITH THE SELF-CARE FRAMEWORK

We would strongly encourage CHPSD not to pursue any proposed changes to definitions in isolation. It is absolutely critical to ensure alignment with how this regulatory lexicon is reflected within the context of the SCF. For example, we note that the term 'importer' is not presently defined within the context of cosmetics or drugs; and although the term is defined in the NHP context (i.e., "to import into Canada a NHP for the purpose of sale"), it adds little in terms of practical clarity or benefit. The last thing these proposals should be looking to introduce is a unique set of definitions specific to cosmetics and personal care products, that would not equally apply to all self-care products, moving forward. On this basis, we welcome further dialogue to better understanding the underlying root of the concern, so that a harmonized and holistic approach could be considered across all low-risk self-care products.

STRENGTHENING NOTIFICATION ENFORCEMENT

CA Canada members appreciate the need for ensuring that appropriate compliance and enforcement tools are enabled through the *Cosmetic Regulations*. Nonetheless, these tools should be risk-based and commensurate with the post-market approach that underpins these Regulations. Given that notification is only required within 10 days of a product being made

available for sale, we would suggest that failure to submit a CNF within the post-market notification window does not necessary mean that a product is inherently unsafe, or that there is a health and safety issue for Canadians, as the Notice would appear to imply.

In this context, although we appreciate the proposal to ensure that appropriate authorities for enforcement are enabled in Regulation, we would suggest that recasting this proposal in a way that provides sufficient flexibility to enable a risk-based outcome would be more appropriate, such that multiple enforcement actions (e.g., notice, warnings, etc.) may first be considered rather than simply the issuance of an 'immediate stop sale order'. Enabling this discretion would allow for meaningful latitude in enforcement to help promote compliance, and more importantly would be more in line with our understanding of Health Canada's risk-based enforcement approach.

Minor note: We would suggest re-positioning the proposal to reflect a provision to strengthen notification enforcement, rather than notification requirement, as it is not the requirement *per se* that is the subject under scrutiny.

INCI NOMENCLATURE ON COSMETIC NOTIFICATION FORMS

The requirement as per paragraph 30(2)(d) of the *Cosmetic Regulations* requiring ingredient names to be provided in cosmetic notifications is clear and well understood. Although we appreciate that the *Cosmetic Regulations* specifically compels ingredients to be disclosed on product labels using INCI names, as outlined in the Notice; we would note that in practice, there may be different processes and systems across and down the supply that a product sponsor may consult when completing a Cosmetic Notification Form, and that not all of these systems may easily or consistently integrate INCI designations. Therefore, although CA Canada appreciates the apparent intent behind this proposal, we respectfully note that Health Canada's presumption that this proposal *"… would not represent additional burden for manufacturers and/or importers…"* may be an oversimplification and may not necessarily be representative across all circumstances.

With this in mind, CA Canada would suggest that it may be more appropriate to contemplate building these considerations in policy guidance, rather than compelling this proposal in Regulation. This will allow for an appropriate degree of practical latitude, recognizing the inherent complexity of certain supply chain systems.

REVISED CONCENTRATION RANGES ON COSMETIC NOTIFICATION FORMS

CA Canada appreciates the flexibility per Section 30(2)(d) of the *Cosmetic Regulations* which allows for Cosmetic Notifications to include either exact concentration information for each ingredient, OR an indication as to the concentration range at which an ingredient is present in formulation (based on prescribed ranges, as set out under this Section). This flexibility is important, as information related to specific concentrations may be considered business sensitive (i.e., confidential business information, CBI) and proprietary. By enabling reporting in ranges, sponsors are able to make a choice as to how ingredient concentrations are reported within the context of a Cosmetic Notification. We are pleased that these flexibilities do not appear to be changing based on the proposals outlined in the Notice.

As for the narrowing of available concentration ranges as proposed, we would encourage further dialogue to understand the basis of the revised ranges, and more importantly to confirm the underlying motivation behind the proposal. Specifically, we would suggest officials consider the following:

- Detailing how the revised ranges were established. The proposed narrowing of the ranges appears to be arbitrary, and it would be helpful to better understand what information was considered to inform them.
- We appreciate the acknowledgement of the 'worst-case' approaches that Health Canada considers when conducting risk assessment and risk management, as described in the Notice.
- Even with the narrowing of these reporting ranges as proposed, Health Canada will continue to defer to worst-case scenarios, which in the absence of more definitive data, we would contend is an appropriately conservative approach. As such it is unclear as to specifically what challenges, if any, that these revised ranges are really looking to resolve.
- CA Canada supports considerations that looks to narrow inherent conservatism and/or encourage more refined exposure estimates to inform risk mitigation efforts, where appropriate.
- If this is the intent behind these proposals, we would suggest that a more effective approach would be to build appropriate internal policy guidance to encourage officials to work with stakeholders to seek more refined use estimates, when necessary.
- We would note however that such a measure would not require the proposed regulatory amendment as outlined.
- Finally, the Notice suggests that the narrowing of these reporting ranges will *"…provide more precise information which would facilitate the screening of cosmetic notification and enhance…"* risk assessment. Furthermore, the Notice also suggests that these measures *"… may reduce the number of clarification requests sent to regulated parties during the screening of cosmetic notifications."* It would be helpful if baseline data to substantiate these proposed benefits could be provided, so that stakeholders can more meaningfully respond to these specific considerations, moving forward.

In the absence of additional information, it is unclear what benefit(s) in reality these proposals are looking to affect. Therefore, we recommend that stakeholders would benefit from a more transparent understanding of the underlying intent behind these proposals, so that additional perspectives can be brought to the fore.

BROADENING WHO CAN BE CONTACTED TO PROVIDE EVIDENCE OF SAFETY INFORMATION

On principle, CA Canada appreciates that the Cosmetic Regulations should enable Health Canada to seek safety information across a reasonable breadth of the supply chain, so to enable meaningful engagement with sponsors where evidence of safety information is being sought. Clarifying who can be contacted in this context to provide such information is an understandable prerogative.

As we understand the current Regulations, Section 29 outlines that:

> *"The Minister may request in writing that a manufacturer submit… evidence to establish the safety of a cosmetic under the recommended or the normal conditions of use."*

The Notice appears to suggest that this provision is only specific to "Canadian" manufacturers; however, we do not believe to be the case, as the current definition of manufactures as outlined under Section 2 is not so specific.

We acknowledge that the majority of product available for sale in Canada are imported, as outlined in the Notice, and consequently we appreciate the proposal to consider expanding the scope of this current provision to include importers. However, in considering whether this proposal will meet the intended objective, we would urge officials to consider the following:

- An importer may not necessarily have access to pertinent information that could address the evidence of safety follow-up.
- Even if an importer has relevant information, they may not be in the position to disclose such evidence, as they may not be the 'owners' of the safety data.
- In the case of third-party manufacturers, it is possible that they would only have limited access to safety information, as this data would reside with the brand owner and not necessarily made available to a contract manufacturer.

With the above considerations in mind, we believe the current provisions as outlined under Section 29 may already be sufficiently broad, as it appears to be focused on the entities with the highest level of responsibility for the cosmetic product in question, where it is most likely the most relevant evidence of safety information would be available.

Nonetheless, we appreciate that there may be challenges with compelling engagement in circumstances where contacts are not based in Canada. Although we understand these challenges, it is unclear at this juncture as to the relative magnitude of missed opportunities that may be attributable to these circumstances, and whether or not the proposal as outlined will promote a different outcome. In this regard, we would strongly recommend pursuing additional dialogue with stakeholders, on how best to ensure that such requests be passed up along the supply chain, as appropriate. However, compelling such action in Regulation, may not be the most effective path forward.

ADMINISTRATIVE CONSIDERATIONS – PROPOSALS 4

UPDATING REFERENCE TO INCI DICTIONARY AND HANDBOOK AND REFERENCE TO CTFA

CA Canada fully supports the proposal to update how the *"… ICI Dictionary (meaning the International Cosmetic Ingredient Dictionary and Handbook…"* is referenced in the *Cosmetic Regulations*. We appreciate the proposal to update the publisher of this Dictionary to reflect the organization name change of the *"Personal Care Products Council"* (from the Cosmetic, Toiletry, and Fragrance Association, Inc.). As for the inclusion of a specific print edition, we would recommend proceeding with a generic citation (without a specific version year), followed instead with the qualifier "as amended/updated from time to time", so to avoid the need for a similar administrative amendment every time the print version is updated. Furthermore, we would also suggest that inclusion of on-line dictionary should also be considered.

CLARIFYING SCHEDULE LANGUAGE TO ENHANCE COMPREHENSION

The underlying motivation behind the proposed administrative update to the format of Schedule 1 is not clear. The current guidance already adequately addresses the interpretation of the Schedule and how it is functionalized. It would be helpful if Health Canada could elaborate on the specific circumstances that suggest the need for such a change. If the basis for this proposal is simply hypothetical, we would question whether any change is even warranted.

INCI NOMENCLATURE – UPDATING OF EU TRIVIAL NAMES

The proposal to update the Schedule to reflect changes to specific EU Trivial Names as they are amended from time to time is reasonable. To facilitate such updates in the future, we would suggest perhaps looking to incorporating an authoritative List of EU Trivial Names by reference, such that separate regulatory amendments do not need to be pursued every time an updated EU Trivial Name is implemented.

FURTHER ENGAGEMENT TO SUPPORT COST-BENEFIT ANALYSIS

CA Canada appreciates the reference to how *"… feedback received during this pre-consultation will be considered in the development of a regulatory proposal, which includes performing a cost-benefit analysis to support regulatory decisions"* which is outlined under the Introduction of the Notice. The integration of such an analysis to support regulatory proposals is an integral feature of regulatory consultations, and we appreciate the opportunity to provide any insights that could help inform or further contextualize such analysis.

In this regard, as noted throughout this submission, there are a number of instances where a fair assessment of the costs and underlying benefits of this proposal may not be easily supported,

given some of the identified uncertainties with the overall rationale behind specific proposals. In this regard, CA Canada would appreciate the opportunity to further engage with such analysis, once some clarifications in response to this commentary is forthcoming. In this regard, we look forward to the opportunity to re-engage with these considerations prior to the proposals being finalized for consultation.

SECTION 3 – ADDITIONAL CONSIDERATIONS TO FACILITATE SELF-CARE FRAMEWORK

As CHPSD considers these modernization reforms, we would strongly encourage Health Canada to take this opportunity to also consider integrating a number of enabling proposals that could ultimately facilitate the implementation of the SCF. Cosmetic and personal care products are an integral part of the SCF, as such, this pre-consultation represents a great opportunity to promote some of the regulatory and policy imperatives that may need to be considered in relation to amendments to the *Cosmetic Regulations* that will ultimately be needed to fully enable the SCF.

In this regard, we would strongly recommend that CHPSD, together with the Self Care Team at NNHPD should consider at least initiating a dialogue to contemplate how these amendments might also be expanded to address the following foundational elements in relation to the SCF:

- Notification system/process
- Good manufacturing practices (GMPs)
- Post market surveillance and adverse event reporting (vigilance) provisions
- Recall provisions
- Risk-based compliance and enforcement approach
- etc.

At a minimum, we would encourage CHPSD to consider how these present regulatory modernization activities can be leveraged to possibly address some of these elements, to help shape, facilitate, and advance the SCF as a key Departmental priority.

REQUEST FOR FOLLOW-UP MEETING(S) TO REVIEW COMMENTARY IN DETAIL (INCLUDING JOINT DIALOGUE WITH OFFICIALS ENGAGED WITH THE SCF)

Due to the nature of some of the commentary outlined herein, CA Canada would like to request the opportunity to further engage with Health Canada officials on these early proposals and to review some of our feedback in more detail. Given the connections and possible implications and overlap related to the SCF, we would also suggest that it may also be opportune to pursue these follow-up discussions in conjunction and collaboration with your colleagues at HPFB who are engaged with the SCF. Given the synergies of topics, and most importantly to make the important connections and bridge this commentary with many of the like proposals that are also presently under consultation regarding labelling reforms under Phase 1 of the SCF, taking a coordinated approach to such follow-up, including some of the additional considerations outlined under Section 3, above, would be an effective and efficient conduit to enabling consistency between related proposals.

SUMMARY AND CLOSING CONSIDERATIONS

CA Canada appreciates the opportunity for early engagement on the concepts outlined in this pre-consultation. These proposals build on previous dialogue with CA Canada and as such, we are largely supportive in principle of the general direction of the core proposals as outlined. We do present a number of questions and/or concerns regarding some of the proposals, particularly, those related to operational oversight considerations, as outlined.

As officials further contemplate and refine these proposals, we would recommend that greater transparency in the underlying rationale and/or supporting data substantiating these proposals would be helpful. It would also be beneficial if a more comprehensive overview of the overall intent and/or regulatory objective(s) of the proposals are presented. Finally, most importantly, many of the concepts outlined in the Notice parallel considerations already presently under consultation within the context of the SCF. It is absolutely imperative for these proposals to be coordinated and 'right sized' with the overall direction of the SCF. In this regard, we cannot stress enough the need to ensure that there is no duplication in efforts, and even more importantly that proposals contemplated under these initiatives do not undermine those already in play in the context of the SCF.

In closing, as this is a Pre-Consultation Notice, CA Canada looks forward to the opportunity to discuss these reflections in further detail, as Health Canada looks to refine these proposals in anticipation of their formal consultation on corresponding proposed amendments in the new year.

Please touch base with me at bmontemayor@cosmeticsalliance.ca or outreach to CA Canada at regulatory@cosmeticsalliance.ca to set up a convenient time for the follow-up dialogue as outlined above. In the interim, we look forward to any additional clarifications in underlying rationale that could be provided, as we look to further engage with these proposals, moving forward.

Kind Regards

(original signed)

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WHO WE ARE

Founded in 1928, Cosmetics Alliance Canada (CA) is the leading Canadian industry association and the principal voice of the cosmetics and personal care products industry. We represent over 150 member companies, including brand owners, distributors, importers, manufacturers, retailers, and suppliers of products and services to the cosmetic and personal (self-care) products industry. Specific self-care products of interest to our members include toothpastes and oral rinses, anti-acne products, antidandruff shampoos, diaper rash creams, medicated and antiseptic skin care products, and primary and secondary sunburn protectants.