

March 10, 2025

Ms. Sally Gibbs
Acting Director General
Environmental Health, Consumer Products and Pesticides Directorate (EHCPPD)
Regulatory Operations and Enforcement Branch (ROEB)
Health Canada

VIA E-MAIL sally.gibbs@hc-sc.gc.ca

**Re: "Health Canada's Risk-Based Compliance and Enforcement Approach for
Fragrance Allergen Disclosure" – Letter to Stakeholders Issued February 21, 2025**

We are writing to acknowledge and thank you for the above-referenced Letter to Stakeholders, clarifying the risk-based compliance and enforcement (C&E) that your Directorate, in conjunction with the Consumer and Hazardous Products Safety Directorate (CHPSD) will be pursuing in relation to the implementation of mandatory contact allergen disclosure provisions introduced with the 2024 Regulatory Amendments to the Canadian Cosmetic Regulations (April 2024). We welcome this letter seeking to 'close the loop' on the compliance dialogue that Cosmetics Alliance (CA) Canada and other Trade Associations and our respective members have been looking to address regarding implementation challenges with the 'Coming into Force' (CiF) provisions for these new disclosure obligations.

LEVELING THE PLAYING FIELD – CONFIRMING COMPLIANCE AND ENFORCEMENT APPROACH

This Letter to Stakeholder was shared generically via the Cosmetic Listserv, and as such, we wanted to confirm that to enable a consistent approach, moving forward, the 'compliance promotion' discretion as outlined would apply to all stakeholders. This is different from the case-by-case approach that formed the basis of individual representations that have been pursued in response to Health Canada's original letter from June 2023, where one-on-one engagement was encouraged. We appreciate this evolution in approach, as it simplifies engagement moving forward, whilst providing for a consistent regulatory backstop to these discretionary considerations. If this isn't the case, CA Canada would very much appreciate hearing from you, to clarify any corresponding conditions.

¹Cosmetics Alliance (CA) Canada Input on Pre-Consultation Notice to Amend the Cosmetic Regulations submitted October 5, 2021

²Cosmetics Alliance (CA) Canada Response to Proposed Amendments to the Canadian Cosmetic Regulations, Including Mandatory Disclosure of Certain Cosmetic Ingredients (fragrance allergens), Published for Consultation February 11, 2023, in Canada Gazette Part 1: Volume 157, Number 6 submitted April 21, 2023.

CONFIRMING COMPLIANCE PROMOTION APPROACH AND COMMUNICATIONS LEADING UP TO THE 'COMING INTO FORCE' DATES

In addition to this communique, CA Canada would like to confirm that your Department will be planning proactive communications and stakeholder outreach as corresponding 'CiF' dates approach, to "... *raise awareness*" with and between regulated parties. This outreach aims to clarify expectations regarding discretionary considerations, aligning with Health Canada's Compliance and Enforcement Policy for Health Products (POL-0001).

Pursuing these proactive communications will be extremely important, especially, to clarify and ensure appropriate consideration of these measures at the retail level, to prevent premature and unnecessary withdrawal of products from distribution channels or from retail shelves, during the stipulated compliance promotion period. As CA Canada's membership comprises retail members, we would strongly suggest that, together with the Retail Council of Canada (RCC), we collectively work with your Office to devise a communication plan, aimed at the retail community, to ensure an appropriate understanding of the spirit behind the discretionary considerations as outlined in your Letter to Stakeholders. CA Canada has already outreached to RCC and confirmed their willingness to collaborate on any outreach material, to provide a common understanding in approach to 'right set' expectations, accordingly. We look forward to hearing how we can support your stakeholder outreach efforts in this regard.

ACKNOWLEDGEMENT OF 'RISK-BASED' APPROACH TO HEALTH AND SAFETY RELATED INCIDENTS, ONCE LABELLING REQUIREMENTS COME INTO FORCE

As always, CA Canada supports Health Canada taking a 'risk-based' approach to address incidents, complaints, and/or observations regarding any of the designated contact allergens, or any other ingredient. CA Canada has long stood on the principle of the need to act, should an immediate and/or imminent health risk be identified, regardless of circumstance. In this case, we would reiterate that the implicated substances (now required to be disclosed) are already known contact allergens, with the primary regulatory objective for these new disclosure obligations to facilitate secondary allergen prevention. As such, should any observations materialize in the interim, to promote greater transparency in assessing any corresponding risks, we would strongly recommend that Health Canada considers the criteria for consumer product incident reporting under the Canadian Consumer Product Safety Act (CCPSA) to support an objective and transparent approach to any such risk evaluations. Although we acknowledge that these 'incident reporting' criteria do not apply directly to cosmetics, CHPSD is familiar with these criteria, and we understand that they are already being voluntarily extended to cosmetics, as appropriate.

ENSURING CA CANADA MEMBERSHIP PUTS 'BEST EFFORT FORWARD (Despite Identified Challenges)

Since proactively tabling the concerns that some of our members (especially, those exclusively in Canadian-specific; or North American supply chains) have expressed regarding CiF provisions, CA Canada has actively encouraged our membership to make 'best efforts' to come into compliance within (or as closely as possible) to the prescribed transition deadlines. We will continue to promote the importance of maintaining these efforts, and that this Letter to Stakeholders should not be seen as a 'license' to take the foot off the 'compliance accelerator', in any way.

A FINAL SUGGESTION – COURTESY OUTREACH TO INDIVIDUAL STAKEHOLDERS THAT TOOK ON CHALLENGE TO ENGAGE WITH HEALTH CANADA OFFICIALS (JUNE 2024)

We understand that Health Canada may have no immediate plans to pursue any other correspondence with stakeholders on this matter. From a stakeholder relations perspective, we would strongly recommend that supplemental follow-ups be pursued with any individual company that took Health Canada up on 'seeking meetings with officials to discuss their specific circumstances' (response to June 2024 communiqué to Trade Associations). Considerable time and resources were committed to make the necessary arrangements to support the presentations pursued with Health Canada over the past four months. In recognition of these efforts, we would suggest that a **courtesy follow-up**, thanking stakeholders for their one-on-one engagement, would go a long way to reassure these stakeholders that their input and engagement mattered.

Although, this may be seen or perceived as an unnecessary, additional step; we would note (given that CA Canada was 'in the room' for the large majority of these meetings), a commitment was shared stipulating that companies should expect to receive a follow-up communiqué directly from 'compliance and enforcement' confirming next steps. Although, each of these parties would have clearly received this generic stakeholder letter directly, we trust that you can understand, how it might be important to 'close the loop' directly, with those parties to which a response was committed.

In closing, CA Canada and our members have long supported the principle of mandatory disclosure of known contact allergens (when backed by clinical and scientific evidence), in line with similar provisions, as established in Europe, the UK and elsewhere in the world. In this regard, our members are committed to bringing these new mandatory disclosure and notification obligations to fruition as soon as possible; however, in a manner that minimizes the need for unnecessary disruption and product withdrawals from the Canadian market.

We look forward to hearing from you to confirm and discuss some of the key follow-up considerations as outlined herein. In the interim, thanks again for 'hearing' our members concerns, and for clarifying these important discretionary considerations.

Kind Regards,
(original signed)



Beta Montemayor
Vice-President and Director, Science, Regulations and Market Access
Cosmetics Alliance (CA) Canada

cc Dennis Price, Director General, Consumer and Hazardous Products Directorate (CHPSD), Health Canada
Geoff Barrett, Director, Risk Management, Consumer and Hazardous Products Directorate (CHPSD), Health Canada
Darren Praznik, President and CEO, Cosmetics Alliance Canada (CA Canada)

WHO WE ARE

Cosmetics Alliance (CA) Canada is the leading Canadian industry trade association representing the cosmetics and personal care industry. Representing over 160 member companies, including brand owners, distributors, importers, manufacturers, retailers and suppliers of goods and services to the cosmetic and personal care (self-care) products industry. Products of interest to our members include toothpastes and oral rinses, anti-acne products, anti-dandruff shampoos, diaper rash creams, medicated and antiseptic skin care products, and primary and secondary sunburn protectants.