COSMETICS ALLIANCE CANADA
The Voice of Canada's Personal Care Products Industry

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February 2nd, 2024

Dr. Jean-François Tremblay
Deputy Minister
Environment & Climate Change Canada (ECCC)
Fontaine Building
200 Sacre-Coeur Blvd
Gatineau, Quebec

Dear Dr. Tremblay,

RE: Summary of Information & Proposals Raised in Our Meeting

Firstly, we would like to thank you for meeting with us to discuss the concerns raised in our correspondence dated December 11th, 2023. The additional information and proposals we conveyed in our meeting are summarized in this follow-up letter.

Proposals to Move Forward

We wish to offer the following proposals to move forward on the issues we have raised. These are based on good regulatory practices and would require ECCC to:

1. **Instruct enforcement officers to directly contact the "responsible party" identified in Health Canada's data base** with respect to any investigation or enforcement action.

2. **Implement transparency and review process for the test methods, calculations, and other tools** used to assess compliance.

3. **Assign a senior manager to coordinate between the compliance (policy) function and the enforcement function.**

4. **Create dispute resolution mechanisms in advance of formal legal action** (as does Health Canada).

5. **Initiate an outside review of how proportionately is applied to enforcemen**t and develop guidelines for going forward.

6. **Implement a pilot program to improve the communication and alignment of ingredient information to users** including:

   (a) Coordinate & align compliance and enforcement with Health Canada for the cosmetic and personal care sector.

   (b) Develop a concurrent or aligned Cosmetic Ingredient "Hot List" with Health Canda for restricted or prohibited ingredients including using the easily identifiable *International Nomenclature of Cosmetic Ingredients (INCI).* This could be undertaken in a "batch process" as used in the CMP, with the first "batches" being ECCC's targeted or priority substances.

7. **Complete Review of ECCC's *Compliance and Enforcement Policy* for CEPA** including undertaking consultations with stakeholders AND adopting good regulatory practices.

Summary of Proposed Good Regulatory Practices

The following is a summary of the seven good regulatory practices we have proposed. Details on each are included later in this follow-up letter:

1. **Understand the Parties Being Regulated**
2. **Provide Meaningful Outreach and Education to Regulated Parties**
3. **Make Information Easy to Find and Use**
4. **Communicate with the Right "Responsible Party"**
5. **Be Transparent with the Testing Methods, Calculations, and Other Processes and Tools Used in Compliance & Enforcement**
6. **Create Dispute Resolution Mechanisms in Advance of Formal Legal Action**
7. **Exercise Proportionality and Common Sense in Enforcement**

Our Concern with ECCC's Approach to Compliance & Enforcement for Products Regulated Under Canada's Food & Drugs Act

Our experience and focus with ECCC's approach to compliance and enforcement is, of course, as it is being applied to cosmetics and other personal care products. These products are defined and regulated under *Canada's Foods & Drugs Act* and its' *Cosmetic, Natural Health, and Non-Prescription Drug Regulations*, and are also the subject of the provisions of the *Cosmetics Annex of the Canada-United States-Mexico Agreement (CUSMA)*. Our concern is that these compliance and enforcement policies and practices do not reflect the intricacies of the products, the existence of Health Canada's concurrent regulatory regime, the provisions of CUSMA, or the practical realities of the business chains in which they are made, distributed, and sold.

In summary, we would submit that ECCC is NOT meaningfully promoting, supporting, or assisting regulated parties in our sector in meeting their obligation to ensure the compliance of their products.

The Fundamental Question: Does ECCC Want to Achieve the Highest Possible Level of Industry Compliance?

Given our experience, we wish to confirm that it is actually a goal of ECCC to promote, encourage, and support the highest level of compliance possible among the industries and products which it regulates?

We would hope that ECCC's intent is not to minimize its "compliance" promotion efforts and rely primarily on the heavy hand of "enforcement" to show "just how tough" the Department can be on "violators". We know that there can always be bad actors who require the use of significant enforcement powers to comply, but we also know that most companies want to be compliant and look to regulators for meaningful tools and assistance to do so.

Cosmetic Industry Compliance is High with Health Canada Regulations

In the case of the cosmetic sector, an Auditor-General's review of Health Canada's cosmetic notification data base found that of over 50,000 notifications filed in a year, only about 50 or 0.1% were non-compliant by including prohibited or restricted ingredients in their products. **That is a**

99.9% compliance rate! We would hope that ECCC would want to achieve this same success with our industry for environmental regulations and we would like to propose how this might be done.

It is Time to Review & Re-Write ECCC's Compliance & Enforcement Policy

The Department's *Compliance and Enforcement Policy for the Canadian Environmental Protection Act, 1999 (CEPA, 1999)* was issued in March of 2001 (in advance of CEPA coming into force in September of that year). Now, nearly a quarter of a century old and likely developed for a very different time and circumstance, the Policy takes a VERY legalistic approach with virtually no priority placed on providing regulated parties with meaningful information, guidance, education, or any other tools that could use to facilitate "compliance" and avoid "enforcement".

We have noted from ECCC's website that the Policy is "under review". If this is the case, we would strongly urge ECCC to make this review a priority and meaningfully engage its' stakeholders - possibly by sectors – to provide input on how it could be modernized. Cosmetics Alliance would request the opportunity to engage in this process.

Further Details on Good Regulatory Practices

We would suggest that these seven good regulatory practices would promote and facilitate in our sector a high level of regulatory compliance with environmental regulations and reduce the current level of frustration. They form the basis of our proposal to move forward and should be represented in a modernized *Compliance and Enforcement Policy.*

1. Understand the Parties Being Regulated

CEPA covers a wide variety of circumstances, industries, and products. A one-size-fits-all approach to regulatory compliance and enforcement rarely is effective across such a large range of circumstances.

In our sector, companies can range from large international organizations to small and medium-sized firms, and even single operators who import or retail small amounts of products. The success of Health Canada's approach to compliance is that they provide simple and easily used tools such as the cosmetic ingredient "Hot List" of restricted and prohibited ingredients.

Consequently, the policy must account for this wide range of users and include meaningful tools that are easily found and used.

2. Provide Meaningful Outreach and Education to Regulated Parties

Regulators need to be pro-active in outreaching to and educating regulated parties to ensure that they have meaningful and useful information to ensure compliance. It also provides the regulator with valuable information, feedback, and insight on how to improve its efforts and communication with regulated parties.

The limits on education, outreach, and providing meaningful information contained in the current *Compliance & Enforcement Policy* undermine this good regulatory practice. Simply advising parties that they can find information they require "in the Canada Gazette" is not only unhelpful, but frustrating.

3. **Make Information Easy to Find and Use**

To be readily applied, compliance materials – such as lists of prohibited or restricted ingredients/substances- must be easy to find (in one place), and easy to use (including familiar nomenclature). This is especially the case for importers matching the list of ingredients in a product to regulatory requirements.

From the perspective of the user who wants to know if an ingredient is legal or not, it does not matter if it is restricted or prohibited for human health/safety or environmental reasons, they **JUST WANT TO KNOW IF THEY CAN USE IT!** And they want to be able to go to **ONE LIST**, presented in the **right INGREDIENT NOMENCLATURE.**

If two Departments are regulating the use of the same ingredients for the same sector, it is essential that they offer a **COMBINED** or **ALIGNED LIST**, in a **COMMON NOMENCLATURE**, and in **ONE COMMON LOCATION**, if they wish to maximize compliance. This is the **KEY** to high compliance rates.

ECCC should be working with Health Canada to produce **ONE** "Hot List" that reflects ingredient restrictions for both human health and environmental reasons.

4. **Communicate with the Right "Responsible Party"**

Effective regulation requires that regulators identify, contact, and communicate with the party who is responsible for the product. For finished consumer and consumer health products regulated under the *Food & Drugs Act,* this is the manufacturer or importer. Canadian law requires that their names and contact information be provided to Health Canada, who also requires a list of the ingredients and their range of concentration in the product. Retailers, unless it is a "house brand", are rarely the responsible party.

It has been brought to our attention that ECCC will often contact retailers about a product rather than the responsible manufacturer or importer. This may unnecessarily undermine the relationship between the retailer and manufacturer or importer, add confusion to the situation, and ultimately delay the resolution of any issue.

Given that the Government of Canada has already established a data base of responsible parties with Health Canada, ECCC should coordinate with Health Canada to access the information and avoid the issues outlined. This would be a "Government of Canada approach."

5. **Be Transparent with the Testing Methods, Calculations, and Other Processes and Tools Used in Compliance & Enforcement**

To be compliant, a regulated party should know by what testing methods, calculations, or other tools the regulator is using to assess their product.

Hiding this information does not promote compliance. It does not allow the regulated party to evaluate their product before going to market. Nor does it allow for challenges to these methods or tools that may demonstrate inaccuracies or other issues that can undermine the credibility of the regulator. Transparency is therefore a key principle of good regulatory practice.

We are aware that ECCC refused to provide the testing method they employed to detect plastic microbeads in various products. When ECCC did finally provide it, the copy was redacted such

that it was unusable, and it was provided to the retailer rather than the manufacturer who required it and is the "responsible party". A complete copy of the testing method was only recently provided to the industry after more than a year of requests, interventions, and significant effort. This is NOT what regulatory transparency should look like!

6. Utilize Dispute Resolution Mechanisms in Advance of Formal Legal Action

There will always be occasions when a dispute can arise between the regulator and the regulated. These can include issues like the validity of test methods, interpretation of limits, identification of substances, etc. Good regulatory practices suggest that a transparent and independent process within the department be established to resolve these matters before they escalate.

Health Canada has established such tools to address their areas of regulatory disputes including a "Reconsideration of Decisions Issued for Human Drug and Natural Health Product Submissions", which includes a formal Guidance Document easily available to stakeholders. Additionally, Health Canada established the *Food & Drug Act Liaison Office (FDALO)* whose mandate is:

> *To receive complaints, concerns, or enquiries about alleged acts, omissions, improprieties and/or broader systemic problem on matters pertaining to the Food & Drugs Act, and to listen to, offer options, facilitate resolution, make recommendations, or otherwise examine the issues impartially.*

Our industry has used these services on many occasions and found them to be a useful tool in resolving issues. ECCC could benefit from an equivalent office as FDALO for CEPA.

7. Exercise Proportionality and Common Sense in Enforcement

Good Regulatory Practices and the experience of Health Canada in our sector suggest that enforcement actions should always come with a good dose of proportionality and common sense.

When companies are genuinely trying to be compliant and want to be cooperative to resolve an issue of which they were unaware, the "enforcement" function should be a tool to correct, educate, and move forward. This should especially be the case if the infraction is proportionately small and has resulted in no appreciable risk.

The full weight of a department's enforcement powers should be reserved for violators who blatantly disregard compliance, are chronic offenders, or where violations have resulted in significant injury or risk.

In our industries recent experience with ECCC enforcement actions, we have observed ECCC:

- Order the destruction of a product containing in total of a few kg's of the substance in question spread over the entire Canadian market over the period of a year.
- Insisting on further recall activity when the distributor has already achieved a 95%+ return rate from stores over which they have no control.

In Conclusion

We would expect that these good regulatory practices and our proposals to move forward would begin to address our concerns as well as the issues raised by the CUSMA agreement.

As we have stated before, the very long-term objective should be to have one regulatory administration to manage compliance and enforcement in our sector for both health and environmental regulations. This would truly be a “one government” approach.

On a final note, we would confirm that we are not disputing or debating the specific regulations of various substances. Our industry has been and remains a supporter of Canada’s world leading Chemicals Management Plan in which we have been actively engaged since its inception in 2006. We also confirm that our meeting did not discuss any ongoing investigations or actions with specific companies and that the members of our delegation did not include anyone from a company currently subject to an investigation or action by your department.

Thank you for your time and attention, and we look forward to your response.

With best regards,

Best regards,

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