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See letter.

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Hazardous Waste and Toxics Reduction Program
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Dear Ms. Franjevic,

ArentFox Schiff LLP respectfully submits the following comments related to the Department of Ecology's (the Department) proposed rulemaking to implement the Washington Toxic-Free Cosmetics Act (TFCA) on behalf of a client that operates as an online retailer and sells cosmetic products (Client).

Retailers operate in very complex global supply chains and work with thousands of vendors to supply a wide range of consumer products, including cosmetic products. Because retailers typically do not manufacture the cosmetic products that they sell, retailers often manage robust vendor and product compliance programs with the entities that actually manufacturer the products. However, even with robust vendor and product compliance programs in place, ultimately the actual manufacturer (*i.e.*, the entity that physically produces the cosmetic product) is most often the entity that is responsible for a product's formulation. By contrast, retailers (and distributors and importers) typically do not have insight into or control over the ingredients that are added to a given product, nor are they in a position to independently verify the ingredients in the products they import, distribute, or sell.

In the absence of clarification from the Department, potential ambiguities in the plain language of the TFCA could (i) put retailers (and importers and distributors) in the impossible position of having to independently verify the ingredients in the cosmetic products that they sell, and (ii) lead to an inequitable imposition of penalties for unknowingly selling a cosmetic product that contains one of the relevant chemicals or chemical classes identified in the TFCA.

The absence of such clarification and the current limit set for trace levels of lead, as discussed further below, will not only prevent the TFCA from providing any intended benefit to Washington consumers, but will in fact result in harm to both Washington consumers and businesses alike.

Client respectfully requests that the Department consider the following feedback and recommendations as it proceeds through the draft rulemaking process.

Clarifying the Knowledge Qualifier

Client would like to express concern regarding potential ambiguities with the use of the term "knowingly" in Wash. Rev. Code § 70A.560.020. As you know, this section of the TFCA provides that, "beginning January 1, 2025, no person may manufacture, knowingly sell, offer for sale, distribute for sale, or distribute for use in this state any cosmetic product that contains [certain intentionally added chemicals or chemical classes]." As written, it is unclear if the term "knowingly" is intended to and does apply to "offer for sale," "distribute for sale," and "distribute for use." Client believes that the term "knowingly" should apply to all the aforementioned clauses, as it would be inequitable to penalize a non-manufacturer entity for the *unknown* addition of one of the relevant chemicals or chemical classes.

Without such clarification, Wash. Rev. Code § 70A.560.020 could be interpreted to prohibit offering for sale, distributing for sale, or distributing for use a cosmetic product that contains one of the prohibited ingredients regardless of whether the selling or distributing party is aware of this fact. This would place entities such as retailers and distributors in the impossible position of having to independently verify the ingredients in the cosmetic products they sell and distribute to comply with Wash. Rev. Code § 70A.560.020. Client therefore recommends that it be made clear via the rulemaking process that Wash. Rev. Code § 70A.560.020 only prohibits the knowing sale, knowing offering for sale, knowing distribution for sale, and knowing distribution for use.

We propose the following regulatory text:

§ 70A.560.020 **Prohibiting the sale of cosmetic products containing certain added chemicals—Department's duties.** (1) Except as provided in subsection (3) of this section, beginning January 1, 2025, no person may manufacture or knowingly sell, offer for sale, distribute for sale, or distribute for use in this state any cosmetic product that contains any of the following intentionally added chemicals or chemical classes:

(a) Ortho-phthalates;
(b) Perfluoroalkyl and polyfluoroalkyl substances;
(c) Formaldehyde (CAS 50-00-0) and chemicals determined by the department to release formaldehyde;
(d) Methylene glycol (CAS 463-57-0);
(e) Mercury and mercury compounds (CAS 7439-97-6);
(f) Triclosan (CAS 3380-34-5);
(g) m-phenylenediamine and its salts (CAS 108-45-2); and
(h) o-phenylenediamine and its salts (CAS 95-54-5).

(2) Except as provided in subsection (3) of this section, beginning January 1, 2025, no person may manufacture or knowingly sell, offer for sale, distribute for sale, or distribute for use in this state any cosmetic product that contains intentionally added lead or lead compounds (CAS 7439-92-1),

lead or lead compounds at one part per million (ppm) or above, or as otherwise determined by the department through rule making.

Increasing Lead Limit

The arbitrary and unprecedented less than one part per million (ppm) standard set for lead or lead components, as provided in Wash. Rev. Code § 70A.560.020 is deeply concerning.

A 1 ppm limit for lead will yield no discernible public health benefit and will only serve to negatively impact Washington businesses and consumers. Notably, 1 ppm is far below the threshold amount for lead in cosmetics set by numerous regulatory bodies both in and outside the United States.

For example, in draft guidance issued in 2016, the United States Food and Drug Administration (FDA) recommended a maximum level of 10 ppm for lead as an impurity in cosmetic lip products and externally applied cosmetics.[1] Importantly, FDA chose this limit because the Agency determined that "up to 10 ppm lead in cosmetic lip products and externally applied cosmetics would not pose a health risk" and that the 10 ppm limit is "achievable with the use of good manufacturing practices."[2] Similarly, a 2013 Report for the International Cooperation on Cosmetics Regulation (ICCR) – whose authors included regulators from Canada, Japan, the United States, and the European Union – also recommended a 10 ppm limit for lead in cosmetics.[3] As such, it is difficult to understand how a 1 ppm limit is suitable here.

In addition to there being no public health benefit, setting a limit of 1 ppm for lead in cosmetics will have a devastating impact on Washington businesses and consumers. Lead is not intentionally added to cosmetics, though a finished product may contain trace amounts due to the addition of natural substances. With that in mind, setting a limit of 1 ppm will force businesses to undertake tremendous efforts to remove trace amounts of lead that pose no risk to human health and safety. This will undoubtedly result in the removal of numerous cosmetics from the market, needlessly preventing business from selling products that pose no safety risk and severely diminishing the options available to consumers.

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[1] FDA, *Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level Guidance for Industry* (Dec. 2016), https://www.fda.gov/media/99866/download.

[2] *Id.*; FDA, *Limiting Lead in Lipstick and Other Cosmetics*, https://www.fda.gov/cosmetics/cosmetic-products/limiting-lead-lipstick-and-other-cosmetics.

[3] ICCR, *ICCR-7: Traces Working Group: Considerations on Acceptable Lead Levels in Cosmetic Products (Excluding products used in the oral cavity)* (Dec. 2013), https://www.iccr-cosmetics.org/downloads/topics/2013-12_recommendation_on_lead_traces_in_cosmetics.pdf.

Clarifying Penalties under the TFCA

Finally, Client would like to encourage the Department to provide clarification regarding the parties to whom the penalty provision of the TFCA applies. As written, the penalty provision of the TFCA does not appear to contemplate the complexity of the cosmetic product supply chain, which, as described further below, is likely to lead to inequities and confusion in the industry.

Wash. Rev. Code § 70A.560.030 provides:

> A manufacturer that produces a product or imports or domestically distributes a product in or into Washington in violation of a requirement of this chapter, a rule adopted under this chapter, or an order issued under this chapter, is subject to a civil penalty not to exceed $5,000 for each violation in the case of a first offense. Manufacturers who are repeat violators are subject to a civil penalty not to exceed $10,000 for each repeat offense.

"Manufacturer," in turn, is defined as "any person, firm, association, partnership, corporation, governmental entity, organization, or joint venture that produces a product or is an importer or domestic distributor of a product sold or offered for sale in or into the state." Wash. Rev. Code §§ 70A.350.010, 70A.560.010.

Under a plain reading of the TFCA, importers and distributors conceivably could be liable under Wash. Rev. Code § 70A.560.030, a troubling possibility given the limited roles that these entities often play in cosmetic supply chains. With respect to cosmetics, the actual manufacturer (*i.e.*, the entity that physically produces the product) is in the best position to determine, control, and test the ingredients in the products. An importer and distributor, by contrast, typically have no control over the ingredients added to any given product, nor are they in a position to independently verify the ingredients contained in the products they import or distribute. Penalizing a distributor or importer due to the presence of ingredients over which they have no control would be a highly inequitable result.

Similarly, Client encourages the Department to clarify in rulemaking that Wash. Rev. Code § 70A.560.030 does not apply to retailers. As with distributors and importers, retailers typically have no control over and are ill-positioned to independently verify the ingredients in any given cosmetic product. In the vast majority of cases, it would be unfeasible for a retailer to test a sample from every lot of every cosmetic product that they sell or offer for sale. As such, it would be unjust for them to incur liability under Wash. Rev. Code § 70A.560.030.

Client thus encourages the Department to clarify in its rulemaking that, when considering the potential imposition of penalties under the TFCA, the Department will look to the entity that is ultimately responsible for the formulation of a cosmetic product.

Client appreciates the opportunity to provide comments as the Department undertakes rulemaking to implement the TFCA and respectfully requests that the Department consider the above comments and suggestions during the upcoming rulemaking process.

Respectfully submitted,

Emily Leongini