

10 Oct 2024 | Analysis

Washington State TFCA Stakeholders: Don't Hold Your Breath For Higher Lead Limit

by Eileen Francis

Toxic-Free Cosmetics Act planner Shari Franjevic acknowledges the Washington State Department of Ecology is authorized to use enforcement discretion regarding the new law's 1ppm limit on trace lead in cosmetic products, effective 1 January 2025, or raise the ceiling via rulemaking. But it does not seem inclined to do either based on data known to the department at present.

Stakeholders facing the fast-approaching 1ppm lead limit under Washington state's Toxic Free Cosmetics Act should conduct analytical testing of products of concern if they haven't already, keeping in mind state regulators have no plans to increase the limit and will only practice enforcement discretion if there is scientific rationale to do so, says the law's implementation planner Shari Franjevic.

Speaking during the 11 September session of the Independent Beauty Association's fall 2024 Cosmetics Convergence Symposium, Franjevic said the Washington State Department of Ecology (DOE) has received "lots of questions, concerns, comments about this 1ppm threshold, and we understand that it's new and different, right? It's lower than what industry has had to do before," she said.

"We understand that behavior change is required. You're going to have to do something to learn more about what the levels are in those ingredients – what is the variability? what does the data really say? – and really try and understand how to meet those new requirements."

The DOE is “open to more information from you as those that are purchasing these ingredients to help us understand, are there certain very specific products or product categories where this 1ppm lead threshold is going to be very difficult to achieve?”

Governor Jay Inslee gave his signature to the TFCA, the most aggressive cosmetic substances ban in the US to date, on 15 May. (A#RS153696)

The law will ban the manufacture, sale or distribution of cosmetic products containing nine chemicals or chemical classes, including lead and lead compounds (at levels at or above 1ppm), formaldehyde, per- and polyfluoroalkyl substances (PFAS), ortho-phthalates, triclosan and methylene glycol, beginning 1 January 2025. The bill also sets a 1 January 2026 deadline for in-state retailers to sell existing stock.

TFCA also authorizes the DOE to conduct rulemaking to identify and restrict formaldehyde releasers. The Department of Ecology announced rulemaking to that effect in May and in June released a proposed list of the first 10 formaldehyde releasers to be prohibited. (Also see "[Washington State Seeks Feedback As It Kicks Off Formaldehyde-Releasers Rulemaking](#)" - HBW Insight, 18 Jul, 2024.) Restrictions will be adopted in mid-2025 and are expected to take effect starting 1 January 2026.

Franjevic said the DOE aims to conduct its economic impact assessment regarding the targeted 10 formaldehyde donors in October, issue a draft final rule in November, and host public hearings in December.

Regarding lead, the Personal Care Products Council filed a petition in June requesting that the 1ppm ceiling be raised, which the department has the authority to do through a rulemaking. However, DOE denied PCPC's request and two similar petitions "because we would need evidence that the 1ppm restriction is not achievable," Franjevic said.

Lead is not intentionally added to cosmetic products but occurs naturally and is sometimes present in raw materials used by the industry, including those that impart color. In a 2010 study, FDA found that more than 99% of cosmetic products it tested had lead levels below 10ppm, with an average of 1.11ppm. (Also see "[FDA Issues Final Lead-In-Lipstick Report, Postpones Decision On Cosmetic Lead Limits](#)" - HBW Insight, 12 Dec, 2011.) Franjevic noted about half the products tested in the FDA study had levels below 1ppm.

Nevertheless, during the session's Q&A, stakeholders continued urging the DOE to consider raising the lead limit and/or practicing enforcement discretion, with one attendee stating he expects many color cosmetic products will be banned. In 2016, By Valenti, which has since moved away from makeup to focus on clean, sustainable skin care, said it scoured the globe for solutions to lead contamination in color cosmetics before throwing up its hands in defeat. (Also see "[By Valenti Organics' Fruitless Quest For Lead-Free Pigments: A Case Study](#)" - HBW Insight, 16 Feb, 2017.)

Franjevic responded that the DOE has no evidence at this time to support excluding any particular products from the restriction. She pointed to a DOE study which found that 17 out of 20 cosmetic products tested had lead concentrations below the 1ppm threshold. That data, along with the FDA testing, "suggests that while not every product in the market today has below 1ppm lead, it is indeed feasible that you can do it. And what we really see is that this is really about communication with your supply chain and control of raw materials as they're coming in."

While not considering a rulemaking to change the lead limit, the DOE does have tools at its disposal to deal with "very specific" issues through enforcement discretion, Franjevic said. "But we need the data in order to do anything different than what is in the law."

The DOE is "open to more information from you, as those that are purchasing these ingredients, to help us understand, are there certain very specific products or product categories where this 1ppm lead threshold is going to be very difficult to achieve?" she asked. "And can we get some more data on what those raw materials are and what those levels are, and what the variability is over time?"

As for revising the 1ppm limit in the future, Kimberly Goetz, legislative coordinator with the DOE's Hazardous Waste and Toxics Reduction Program, said that would require the DOE to show the change is the "best approach" and not based on anecdotal input from companies.

From an enforcement standpoint, "it's within our discretion to decide how we can go about doing that and what things come to the top of the pile to be enforced and what things are lower on the list of priorities," she said. However, there must be "clear and convincing" evidence.

Identify Priorities For Testing, Garner Supplier Data

While companies subject to the Evergreen State's TFCA are responsible for ensuring their products are compliant, they are not required to test and provide results to the DOE, nor are they required to use any prescribed analytical test methods, Franjevic said.

"We do provide information on the test methods that we have used through the product testing that we have done, for example, for the cosmetics [report](#)" sent to the state legislature, she said.

When analyzing products or materials for lead, Franjevic said companies should begin with a sense of which formulas/ingredients to test, as there are very specific ingredients and products that typically harbor trace levels of lead, she said.

“There are mineral-based colorants that we know can contain lead impurities, and then clay-based products ... so understanding which ingredients might have that lead in it” is the first step, she said.

Next, companies should confer with suppliers “to really understand what is the lead level that’s coming in, what’s the variability? How do you specify that? What kind of tests do you do? How much data can they provide to you?”

A [guide](#) DOE made available to stakeholders in April suggests that in order to build a comprehensive list of potential sources of lead among raw materials purchased and used, companies should ask suppliers for a composition statement, which is a full disclosure of both an INCI list and incidentals, as well as an impurity statement or certification, among other data.

“There’s a lot of different strategies that we try to articulate in the guidance document about how to start these conversations, but it’s really about learning where it’s coming from in your specific products, learning about your specific suppliers and what they know about the impurity levels in those ingredients,” Franjevic said.