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October 16, 2024

ATTN: Stacey Callaway
Washington State Department of Ecology
300 Desmond Drive, SE
Lacey, WA 98503-1274

Re: *Safer Products for Washington Cycle 1.5 Preliminary Draft Rule*

Dear Ms. Callaway:

On behalf of the Consumer Healthcare Products Association (CHPA)[1], thank you for the opportunity to comment on the Washington State Department of Ecology's (DOE) Safer Products for Washington Cycle 1.5 preliminary draft rule. Upon examining the initial draft rule language and participating in several DOE-hosted webinars, we have identified concerns regarding the Department's proposed definition of "apparel." Specifically, we oppose reusable menstrual underwear, an over-the-counter (OTC) medical device, be categorized as a covered product. Additionally, we have reservations about certain phrasing in the preliminary draft, particularly concerning the definition of "intentionally added per- and polyfluoroalkyl substances (PFAS)" and the concept of "credible evidence."

Threshold for Total Organic Fluorine Detection

The current draft of the proposed rule lacks a specified threshold for total organic fluorine that would trigger DOE's presumption of intentionally added PFAS. Instead, the rule suggests that any detection of total fluorine implies deliberate PFAS addition. Given that total fluorine measurements cannot distinguish between different fluorinated compounds, we consider this testing approach imprecise. We therefore request the adoption of alternative, more specific testing methods.

Additionally, CHPA recommends establishing a de minimis threshold of 100 parts per million (ppm) for total organic fluorine. This approach aligns with Washington's Children's Safe Products Act (CSPA), which employs a 100 ppm threshold for contaminants. Implementing this standard would align the Safer Products for Washington program with established state protocols for regulating chemicals of concern.

Definition of Credible Evidence

We have additional concerns regarding the current definition of credible evidence, which lacks adequate specificity and fails to provide appropriate channels for potential rebuttal. The existing language, as drafted, provides covered product manufacturers with insufficient opportunity to challenge decisions made by DOE.

[1] The Consumer Healthcare Products Association is the Washington, D.C. based national trade association representing the makers and marketers of over-the-counter (OTC) medicine, dietary supplements, and OTC medical devices.

The current definition states:

"*Credible evidence" means information, data, or sources relevant to demonstrate that a priority chemical was not intentionally added to a priority consumer product. Ecology determines what qualifies as "credible evidence" on a case-by-case basis*."

This definition leaves manufacturers at a disadvantage due to its vague nature and the unilateral decision-making power it grants to DOE. To address these issues, we propose that DOE provide more detailed criteria for what constitutes "credible evidence". Additionally, we recommend establishing a transparent and collaborative review process. Furthermore, we suggest implementing a formal mechanism for manufacturers to appeal decisions they believe to be incorrect.

By incorporating these elements, DOE can ensure a fairer, more transparent process that balances regulatory needs with manufacturers' rights to due process. This approach would foster a more cooperative relationship between DOE and product manufacturers, ultimately leading to more effective and equitable implementation of the regulations.

Consider Exempting FDA Regulated Medical Devices

The regulation of medical devices, including their safety and efficacy, falls under the purview of comprehensive federal oversight. This regulatory framework considers a wide range of factors, with particular emphasis on product quality and chemical composition.

We contend that the current classification of reusable menstrual underwear as "apparel" within this regulation is inappropriate. These products are FDA-regulated ,510(K) exempt medical devices and should be treated as such.[2] Their inclusion in the "apparel" category fails to recognize their unique status and the rigorous federal standards to which they are already subject.

Given this context, we respectfully propose that all medical devices be granted an exemption from this regulation, similar to the exemption already in place for drugs. This approach would acknowledge the distinct nature of medical devices and prevent unnecessary regulatory overlap. It would also ensure that these products continue to be governed primarily by the established federal regulations that are specifically designed to address their unique characteristics and uses.

This exemption would maintain regulatory consistency, avoid potential conflicts between state and federal requirements, and recognize the thorough oversight already in place for medical devices. It would also prevent unintended consequences that could arise from subjecting medical devices to regulations not specifically tailored to their unique nature and purpose.

[2] See FDA medical devices product code NUQ. Accessed from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NUQ on October 14, 2024.

Conclusion

CHPA and our members are deeply committed to providing consumers with products that are both effective and safe. We value the opportunity to share our perspective and appreciate your thoughtful consideration of the concerns we have raised.

Respectfully submitted,

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