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July 20, 2025

ATTN: Stacey Callaway
Washington Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

RE: Comments on Safer Products for Washington Cycle 1.5 Proposed Rule – WAC 173-337

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 proposed rule. After careful review of the proposal, we have significant concerns regarding two key aspects of the rule: first, the categorization of reusable menstrual underwear and reusable incontinence products as apparel, which we believe is inappropriate given their function and intended use; and second, the presumption that total fluorine presence necessarily indicates intentionally added PFAS, which may lead to inaccurate regulatory determinations.

Medical Devices Improperly Categorized as Apparel

We strongly oppose the proposed rule's classification of FDA-regulated medical devices, including reusable menstrual underwear and reusable incontinence products, under the "apparel and accessories" definition in WAC 173-337-025. This categorization is fundamentally inappropriate because these products function as 510(k) exempt medical devices subject to comprehensive federal regulatory oversight, not conventional clothing items.

These healthcare products serve distinct medical and health purposes, requiring specialized materials and engineering to ensure user safety, efficacy, and protection. Their classification as "apparel and accessories" ignores their medical function and undermines the established federal regulatory framework governing their safety and performance standards. Unlike conventional clothing, these medical devices undergo rigorous testing and regulatory oversight under federal medical device regulations that do not apply to standard apparel.

We respectfully request that the Washington State Department of Ecology explicitly exempt all FDA-regulated medical devices, including reusable menstrual underwear[2] and reusable incontinence products[3], from the "apparel and accessories" definition in the proposed rule.

Total Fluorine Testing Presumption

[1] Consumer Healthcare Products Association is the Washington, D.C. based national trade association representing the makers of over-the-counter medicines, dietary supplements, and medical devices.
[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=nuq
[3] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=727547&lpcd=EYQ

We have serious concerns regarding the proposed rule's presumption that "Ecology presumes the detection of total fluorine indicates the intentional addition of PFAS." This presumption lacks scientific foundation and will create substantial regulatory and economic burdens for both industry and the Department.

Scientific Limitations with Total Fluorine Testing

Total fluorine detection is an unreliable indicator of intentionally added PFAS for several critical reasons. Natural fluorine occurs in fluoride salts commonly present in water and soil, meaning total fluorine analysis will generate false positives from products containing naturally occurring fluorine compounds. Additionally, this approach fails to account for unavoidable trace impurities that may contain fluorine compounds unrelated to intentional PFAS addition, resulting in misleading regulatory determinations.

Administrative and Economic Burden

The total fluorine presumption will impose significant burdens on all stakeholders. Manufacturers will incur substantial costs and administrative effort to rebut inaccurate claims of intentionally added PFAS, even when no intentional PFAS use occurred. The Department of Ecology will face resource strain from validating numerous rebuttal submissions, creating program implementation inefficiencies. Most concerning, legitimate products may face market restrictions based on false positive results, ultimately harming both businesses and consumers who depend on these products.

Recommended Solutions

Medical Device Exemption

We urge the Department to establish a clear exemption for all FDA-regulated medical devices from the apparel and accessories category, recognizing their distinct regulatory status and essential healthcare function. This exemption would acknowledge the existing federal oversight structure while preventing inappropriate categorization that could disrupt access to critical healthcare products.

De Minimis Threshold

Should the Department proceed with the total fluorine detection standard, we strongly recommend establishing a de minimis threshold of 100 ppm to eliminate reporting and rebuttal requirements for trace-level fluorine content unrelated to intentional PFAS use. This threshold would eliminate false positives from naturally occurring fluorine, reduce administrative burden on both manufacturers and the Department, focus regulatory attention on products with meaningful PFAS content, and align with established scientific best practices for chemical regulation.

Alternative Testing Methods

We encourage the Department to collaborate with industry stakeholders to develop more precise analytical methods capable of accurately distinguishing between intentionally added PFAS and naturally occurring or trace fluorine compounds. Such collaboration would ensure regulatory effectiveness while minimizing unintended consequences for legitimate products and their users.

Conclusion

The proposed rule requires significant revision to address the concerns outlined above. The current framework risks creating barriers to essential healthcare products while imposing administrative burdens based on scientifically imprecise testing standards. To address these issues, we respectfully urge the Department to exempt all FDA-regulated medical devices from the apparel and accessories definition, either remove the total fluorine detection presumption or establish a 100 ppm de minimis threshold, and engage in comprehensive stakeholder consultation to develop more scientifically sound testing and regulatory approaches.

We recognize and appreciate the Department's commitment to protecting public health and environmental safety. We share these important goals and believe that through collaborative engagement, we can develop a final rule that achieves meaningful PFAS reduction while preserving access to essential healthcare products and avoiding unintended consequences for legitimate businesses.

Thank you for your consideration of these comments. We welcome the opportunity to provide additional technical information and engage in further dialogue to support the development of an effective and scientifically sound final rule.

Respectfully submitted,

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