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February 3, 2023

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Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

RE: Docket No. EPA–HQ–TRI–2022–0270 ''Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting''

The Consumer Healthcare Products Association (CHPA)[1] appreciates the opportunity to comment on the recently proposed rule[2] outlining EPA's approach to per- and polyfluoroalkyl substance (PFAS) reporting requirements and to supplier notification for chemicals of special concern under the Toxic Release Inventory program. CHPA is supportive of the goals of reporting requirements for PFAS but has concerns with the proposed changes to Supplier Notifications and removal of the *de minimis* threshold for substances of special concern.

CHPA is concerned that the lack of a clear definition of what constitutes an "article" may lead to EPA, downstream entities, and others not receiving the intended information. As such, we ask that EPA provide additional clarity regarding the definition of "article." Specifically, we respectfully submit that consumer medical devices, drugs, and dietary supplements, and their respective packaging units, constitute "articles," given that they are (1) "formed to specific shape or design during manufacture," (2) have "end use functions dependent in whole or in part upon its shape or design during end use," and (3) do "not release a toxic chemical under normal conditions of processing or use of that item at the facility or establishments." 40 C.F.R. § 372.3. This is supported by OSHA's conclusion that various medical devices are articles under the Hazard Communication Standard.[3]

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[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

[2] Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting. *Fed Reg* 87(232): 74379-74387, December 5, 2022

[3] https://www.osha.gov/laws-regs/standardinterpretations/1990-01-05. The TRI definition of an "article" is largely based on OSHA's Hazard Communication Standard. 53 Fed. Reg. 4500-7 (Feb 16, 1988). Notably, EPA's definition is broader in that fluids and particles are not excluded. *Compare* 40 CFR § 372.3 *with* 29 CFR 1910.1200(c). Moreover, the Hazard Communication Standard's inclusion of some drugs is based principally on the risk of employee exposure, not the possibility of environmental releases. *See* 53 Fed. Reg. 29822, 29838-9 (Aug 8, 1988).

Accordingly, these products should be exempt from both the calculation of whether the 100-pound threshold is met for reporting to EPA[4] as well as from downstream notification requirements (for packaging).

If drugs, dietary supplements, and consumer medical devices (and their respective packaging units) are not considered "articles", removing the *de minimis* exemption would greatly increase the number of potentially impacted entities as manufacturers no longer have a lower limit to determine whether any reporting obligation might be triggered. Further, determining the amount of PFAS contained in products (e.g., packaging) purchased from a supplier would not be practicable and increases in the practical quantitation limit for PFAS chemicals would also place an additional burden on manufacturers with no improvement in the information received by EPA.

Removal of the *de minimis* threshold will also significantly increase the number of necessary supplier notifications leading to a significant change in practice, development of data systems and processes to capture, transmit and retain supplier notifications. Upstream manufacturers would be burdened with having to provide the same information into many unique systems established by their customers. We feel that the burden of this transition has not been adequately captured by EPA in their estimates.

Additionally, as noted in the Economic Analysis, the Agency did not include the number of potential firms impacted because they were not able to estimate the number of additional facilities who may be subject to Toxics Release Inventory reporting due to the removal of the *de minimis* exemption for supplier notification requirements. CHPA recommends the Agency retain the current *de minimis* threshold and revise the supplier notification requirements and capture the burden accordingly.

CHPA and our members thank you for considering these comments.

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[4] Except with respect to manufacturing of articles, which is not subject to the exemption. *See* https://ordspub.epa.gov/ords/guideme_ext/f?p=guideme:qa:::::qa:19-442