NACWA
A Clear Commitment to America's Waters

June 16, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Submitted via *www.regulations.gov*

Re: Docket No. FDA-1975-N-0012, RIN 0910-AF69

The National Association of Clean Water Agencies (NACWA) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposed rule, *Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record*. NACWA represents the interests of nearly 300 publicly owned wastewater treatment agencies nationwide, serving the majority of the sewered population in the U.S. NACWA is leading a campaign, *Toilets Are Not Trash Cans!*, focused on product stewardship efforts to keep harmful products, including triclosan, out of the sewer system. The FDA's proposal would require additional data to establish triclosan and other antibacterial chemicals used in consumer antiseptic washes as safe and effective. Due to concerns about the impacts of antiseptic chemicals on the wastewater treatment process and on the environment, NACWA members support restrictions of the use of antiseptics in consumer products and the FDA's proposal to require additional data about these chemicals.

Wastewater utilities serve the public by protecting human health and the environment, meeting increasingly stringent Clean Water Act (CWA) requirements for the treatment of wastewater. The CWA gives utilities the authority to regulate industrial and commercial discharges of pollutants that may interfere with the wastewater treatment process or that may pass through the facility untreated into the effluent or biosolids (the liquids and solids, respectively, remaining after wastewater treatment). However, utilities have no authority to regulate domestic discharges of pollutants, such as chemicals found in consumer products. Antibacterial soaps and other consumer antiseptic washes are rinsed down the drain and directly into the sewer system. Since wastewater treatment utilities were not designed to remove triclosan and other antiseptics from wastewater, regulation of these chemicals by the U.S. Environmental Protection Agency (EPA) and the FDA at their source is the most practical means of controlling their discharge into wastewater and preventing adverse impacts on wastewater utilities, human health, or the environment.

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Impacts of Antiseptic Products on Wastewater Treatment and the Environment

The proliferation of consumer antiseptic washes, and the corresponding increase in the concentrations of triclosan and other chemicals in wastewater influent, has raised many potential issues with wastewater treatment utilities and with the bodies of water that receive effluent from these utilities. Most of the research available regarding these potential issues focuses on triclosan and triclocarban, the most common chemicals found in antiseptic consumer washes. These issues are highlighted below, with a comprehensive review of the environmental impacts of triclosan and triclocarban available in "On the Need and Speed of Regulating Triclosan and Triclocarban in the United States" by Rolf Halden.[1]

- The wastewater treatment process uses beneficial bacteria and other micro-organisms to break down the organic matter in the wastewater. Studies have shown that triclosan continues to be toxic on bacteria after it is released into the aquatic environment with treated wastewater effluent.[2] Triclosan and other antibacterial ingredients may therefore also potentially harm the beneficial bacteria used to treat wastewater, reducing the effectiveness of the treatment process.

- Approximately 2-3 percent of triclosan and triclocarban from wastewater passes through the treatment process and is discharged with the effluent into receiving waters.[3,4] The presence of triclosan may contribute to failure of whole effluent toxicity (WET) tests, which utilities must conduct on their effluent as part of their CWA permit requirements. WET tests measure the combined effects on aquatic organisms of all pollutants contained in a wastewater utility's effluent. Failure of a WET test may result in substantial costs for utilities due to requirements for additional testing and evaluation of the causes of toxicity.

- In the aquatic environments that receive wastewater effluent, triclosan attaches to the surface of suspended solids and sediments, and can be released into the water again when the sediments are disturbed. Triclosan and triclocarban have been shown to bioaccumulate and to have detrimental effects on aquatic life, including algae, crustaceans, and fish.[2,5]

- Most of the triclosan and triclocarban contained in wastewater partitions to solids and is therefore present in the biosolids produced by the wastewater treatment process.[3,4] Many wastewater utilities use their biosolids as fertilizers or soil amendments, and the presence of triclosan has been detected in crops grown in biosolids-amended soils.[6] Regardless of the effects or lack thereof of these low levels in crops, the presence of triclosan in biosolids may have negative impacts on the ability of a utility to manage those biosolids simply because of the perception that the biosolids are somehow "contaminated." For utilities that incinerate their biosolids, carcinogenic dioxins may be released due to the burning of triclosan, making it more difficult for utilities to meet their Clean Air Act requirements.[7]

Many wastewater utilities are currently working to recover the resources available from wastewater treatment, pursuing reuse of effluent, use of biosolids as fertilizers and soil amendments, and recovery of energy from incineration of biosolids. The viability of this resource recovery depends on the ability of utilities to protect wastewater as a resource, keeping persistent and harmful chemicals out of wastewater whenever possible. The effectiveness of the wastewater treatment process must also be protected from these chemicals. As stated earlier, utilities have the authority to regulate industrial and commercial sources to prevent the introduction of

chemicals into the sewer system, but have no control over chemicals that are used in domestic settings and disposed of down the drain. Better regulation of consumer products containing triclosan, triclocarban, and other antiseptics is therefore needed to keep these chemicals out of the sewer system. While EPA is currently reviewing the use of triclosan as a pesticide, the vast majority of triclosan uses are for FDA-regulated consumer products that are washed down the drain. FDA must therefore consider the full range of wastewater and environmental impacts of triclosan and other antiseptic chemicals when approving the use of products containing these chemicals.

Comprehensive Review of Antiseptic Products Needed

NACWA has provided comments to EPA several times in the past on the use of triclosan in consumer products, most recently in May 2013 to support the Agency's triclosan registration review plan for a subset of the uses of triclosan regulated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). These products include textiles, housewares, and construction and building materials. However, as NACWA noted in those comments, the products containing triclosan that are regulated by FDA – such as soaps and toothpaste – contribute far more to the triclosan content of wastewater since they are washed or disposed of directly down the drain and into the sewer system.

To better protect human health and the environment, as well as protect the wastewater treatment process, EPA and FDA should coordinate their evaluation of chemicals like triclosan that are regulated by both agencies. The overall impacts of triclosan and other antiseptic ingredients will not be understood, and appropriate regulatory actions cannot be taken, without a full evaluation of the life cycle and cumulative exposure to these chemicals from all sources.

Thank you for your consideration of our comments on this proposed rule. Please contact me at 202-533-1836 or *cfinley@nacwa.org* if you have any questions about NACWA's comments.

Sincerely,

Cynthia A. Finley, Ph.D.
Director, Regulatory Affairs

References

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