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April 5, 2022

The Honorable Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration

Submitted via the Federal eRulemaking Portal:

<https://www.regulations.gov/>

***Re: NACWA Comments on the U.S. Food and Drug Administrations
"Standards for the Growing, Harvesting, Packing, and Holding of
Produce for Human Consumption Relating to Agricultural Water"
(Docket ID FDA-2021-N-0471)***

Dear Honorable Dr. Califf:

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) on its proposed *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water* (FDA-2021-N-0471) published in the Federal Register.¹

NACWA represents the interest of 350 public clean water utilities of all sizes across the country that provide an essential service of managing billions of gallons of the nation's wastewater in a manner that ensures the continued protection of public health.

Many of our members are actively engaged in the practice of beneficial water reuse and recycling now or are looking to increase their role in water recycling in the future for a variety of fit-for-purpose uses, including providing alternative water supplies for municipalities, expanding water supplies for agriculture and industrial processes, replenishing groundwater aquifers and mitigating ground subsidence or salt water intrusion, and increasing climate resilience and bolstering environmental restoration.

As FDA considers these comments, NACWA also encourages FDA to consider comments submitted our sister association, the WaterReuse Association, a non-profit organization whose members are dedicated to

¹ 86 Fed. Reg. 69120 (Dec. 6, 2021).

advancing sound state and federal laws and regulatory policies for beneficial water recycling and reuse.

NACWA requests FDA make several clarifications before finalizing this rulemaking as it relates to farmers and growers that receive and use water from treated, recycled municipal wastewater and adjacent farmlands that may receive treated municipal biosolids. These clarifications will help alleviate confusion and provide the necessary regulatory certainty for farmers and growers when it comes to understanding and navigating the diverse and innovative water recycling efforts around the country.

NACWA Recommends FDA Consider a Similar Water Assessment Exemption for Municipal Wastewater Recycling Efforts

Under the existing produce safety regulations, farmers and growers of certain covered produce are not required to test agricultural water that they receive from a Public Water System or public water supply.² While the proposed rule provides farmers and growers of covered produce the same exemption from conducting a water assessment when the water originates from a Public Water System or public water supply, it fails to include parallel exemption provisions for farmers or growers of covered produce that may use treated, recycled municipal wastewater which is similarly regulated for microbials and pathogens under the Clean Water Act.³

The Clean Water Act requires the U.S. Environmental Protection Agency (EPA) to develop and publish water quality criteria that accurately reflects the latest scientific knowledge of all identifiable impacts to public health and the environment that might be expected from pollutants present in water.⁴ Accordingly, EPA is required to update water quality criteria from time to time as new science or technical information becomes available. While water quality criteria developed by EPA are recommendations, states with authorized Clean Water Act authority usually adopt values as-is or even pass more stringent values upon incorporation into state water quality standards.

EPA has a long history of protecting the public from potential harmful viral and microbial pathogens that may be present in water resources. Most recently, in 2012, EPA published its Recreational Water Quality Criteria for Bacterial Indicators of Fecal Contamination that includes specific criteria reflecting the latest scientific understanding and most conservative public protections for those recreating in water-contact activities.⁵ These activities include situations where bodily contact with the water occurs as well as immersion and ingestion of water is likely

² See 21 C.F.R. § 112.46(a)(1–2) (exempting farmers and growers of covered produce from testing agricultural water if they receive water from a Public Water System that meets microbial requirements under the Safe Drinking Water Act and can provide results or a certificate of compliance, or alternatively, if water is received from a public water supply that also meets microbial testing requirements and can be demonstrated by a certificate of compliance.).

³ 86 Fed. Reg. 69132.

⁴ 40 U.S.C. § 1314.

⁵ U.S. Environmental Protection Agency, RECREATIONAL WATER QUALITY CRITERIA (2012).

and uses fecal pollution as an indicator of bacterial contamination—which at its core is a similar premise of FDA’s Produce Safety Regulation—to protect the public from produce-borne pathogen outbreaks.

EPA’s 2012 Recreational Water Quality Criteria helped drive FDA’s 2015 Produce Safety Rule and is recognized in the current proposed rule’s preamble.⁶ Based on the latest science, EPA recommended criteria for culturable *E. coli* in freshwater measured by geometric mean (GM) is 126 culture forming units (CFU) per 100 milliliters (mL) or measured by statistical threshold value (STV) is 410 CFU per 100 mL.

Farmers and growers using agricultural water from municipal wastewater recycling activities that comply with these criteria or state water quality standards under the Clean Water Act and can demonstrate they are meeting these results or provide a certificate of compliance should also be exempt from conducting a water quality assessment. Current water recycling and reuse efforts implement a variety of processes to treat and disinfect wastewater to high purification standards and fit-for-purpose uses, like crop irrigation and other agricultural uses. NACWA recommends FDA add this exemption for treated municipal recycled wastewater used for agricultural activities into the proposed rulemaking.

NACWA Appreciates FDA’s Recognition of Clean Water Act Part 503 in the Continued Protections of Municipal Biosolids on Land

This proposed rule requires farmers and growers to identify the potential for outbreak hazards on adjacent and nearby land uses. NACWA and its members are pleased FDA recognizes the continued role the Clean Water Act and regulations laid out in 40 CFR Part 503(d) protect public health and the environment from pathogens in land applied biosolids.

Municipally derived biosolids are subject to stringent Clean Water Act requirements.⁷ Accordingly, municipal biosolids that are land applied must follow stringent standards that are based on extensive data, research, and risk assessment work, and adhere to management practices and uses that are designed to be protective of human health and the environment.

NACWA members actively manage and treat millions of tons of biosolids generated as a necessary byproduct of the wastewater treatment process. Land application to treated municipal biosolids is a long-proven practice considered to be a safe, environmentally friendly and sustainable beneficial use and continues to be a favorable option for farmers and growers. NACWA appreciates FDA’s acknowledgement that the land application of treated, municipal biosolids subject to Clean Water

⁶ 86 Fed. Reg. 69142.

⁷ See 40 C.F.R Part 503(b) (detailing general requirements, pollutant limits, management practices and stringent operational standards for reducing pathogens and vector attraction for the land application of biosolids).

Act Part 503 provides adequate pathogen mitigation and is not reasonably likely to introduce hazards on adjacent or nearby lands.

Conclusion

NACWA and its members appreciate the opportunity to provide comments to FDA on its proposed rulemaking to update its produce safety regulations and agricultural water provisions. We urge the Administration to include an exemption for municipal water recycling initiatives that offer identical microbial reductions in their advanced treatment and appreciate FDA's recognition that our members' residual management of biosolids provide the necessary public health and environmental protections against pathogens.

If there are any questions, please do not hesitate to contact me at eremmel@nacwa.org or 202/533-1839.

Sincerely,

A handwritten signature in black ink, appearing to read "Emily Remmel". The signature is fluid and cursive, with a large loop at the end.

Emily Remmel
Director of Regulatory Affairs