

April 5, 2022

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

Re: Docket ID No. FDA-2021-N-0471

Dear Commissioner Califf:

On behalf of the WateReuse Association (WateReuse), I am pleased to submit our comments to the U.S. Food and Drug Administration (FDA) regarding the proposed rule on the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water."

The WateReuse Association is a not-for-profit trade association for water utilities, businesses, non-profit organizations, and research entities that advocate for policies and programs to advance water recycling. WateReuse and its state and regional sections represent nearly 250 water utilities serving over 60 million customers, and over 200 businesses and organizations across the country.

WateReuse is responding to the provision within the proposed rule specifically related to water reuse practices that covered farms might use for pre-harvest agricultural water. As currently drafted, this provision fails to adequately provide growers that have been safely using municipally treated, recycled wastewater to irrigate produce with a reasonable way to assess risk and document their management practices, and therefore jeopardizes growers' continued ability to use this water source.

Our comments on this rule fall into two categories: (1) recommended modifications to the proposed exemptions for growers meeting certain conditions, and (2) recommended modifications to the agricultural water assessment process.

**Part (1): Recommendations Related to Proposed Exemptions**

The proposed rule provides an exemption from conducting an agricultural water assessment for growers utilizing water received from a public water system. The exemption applies if the grower can demonstrate, through a public water system test result or certificate of compliance, that the water either meets the microbial requirements of the Safe Drinking Water Act (SDWA) or the microbial water quality criterion in § 112.44(a).

These exemptions, while justified and important, would not adequately cover the practice of irrigating produce with treated, recycled wastewater because it imposes an undue burden solely on the grower to demonstrate the safety of the water supply. For many years, growers have been safely using municipally treated, recycled wastewater

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to irrigate produce. In fact, for irrigated agriculture, municipally-supplied, advance treated recycled water is one of the most common non-traditional water supply. Across our hundreds of utility members, engineering firms, and our state sections, we are not aware of a single food-borne outbreak that has occurred as a result of the use of municipally sourced recycled water for irrigation

Current technologies are such that wastewater can be treated to any water quality level for any intended purpose, including irrigation for food crops. This concept is referred to as “fit-for-purpose” treatment. In the case of produce irrigation, while the recycled water is typically not treated to drinking water standards, nor is it always treated to meet a non-detect standard for generic *E. coli*, it is treated to a level demonstrated to be safe for the specific use for irrigated food crops.

§ 112.43(b)(2) and § 112.44(c)(2) of the proposed rule exempt growers from conducting an agricultural water assessment for pre-harvest agricultural water for non-sprout covered produce if the grower can demonstrate that they receive the water from a public water supply that furnishes water that meets the non-detect threshold for generic *E. coli*, and can demonstrate that the water meets this requirement through a test results or certificates of compliance from the water supplier.

**We recommend that this exemption be revised in two ways:**

- **First, the rule should add “publicly owned treatment works<sup>1</sup>” to allow the exemption to cover recycled water supplied by both drinking water treatment systems *and* by wastewater treatment systems. We recommend § 112.43(b)(2) be modified to read as follows [new text underlined]: “Meets the requirements in § 112.44(c) for water from a publicly owned treatment works, Public Water System or public water supply; or”.**
- **Second, the microbial water quality criteria for generic *E. coli* should be revised upward to conform with the microbial water quality criteria established by the 2015 produce safety final rule for pre-harvest agricultural water. We recommend § 112.44(c)(2) be modified to read as follows [new text underlined, deleted text in strikethrough]: “You receive the water from a public water supply that furnishes water that does not exceed a GM of 126 or less colony forming units (CFU) generic *E. coli* per 100 mL and an STV of 410 or less CFU generic *E. coli* per 100 mL, or an equivalent state standard~~meets the microbial quality criterion in paragraph (a) of this section, and you have public water system or wastewater system results or certificates of compliance that demonstrate that the water meets that requirement; or...~~”.**

As FDA itself notes in the preamble to the rule, this standard, which consist of a GM of 126 CFU generic *E. coli* per 100 milliliters (mL), “is the best science currently available that is broadly applicable to the range of conditions that exist across the diversity of operations, agricultural water sources, and agricultural water uses of domestic and foreign covered farms. Therefore, if a covered farm decides to test its pre-harvest agricultural water for generic *E. coli* under proposed

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<sup>1</sup> “Publicly owned treatment works” as defined under the Clean Water Act (40 CFR § 403.3 – Definitions).

§ 112.43(d) to inform its agricultural water assessment, the farm may use a GM of 126 or less CFU generic *E. coli* per 100 mL and an STV of 410 or less CFU generic *E. coli* per 100 mL as microbial criteria.” Water that meets this standard should be exempted under § 112.43(b)(2) and § 112.44(c)(2) from water assessment requirements, provided a grower receives either a demonstration of water/wastewater system results or a certificate of compliance. While growers raised concerns over the cost of compliance with the 2015 testing requirements, the burden of proof for this exemption would now fall to the water supplier (utility or district), not to the grower.

## **Part (2): Recommendations Related to Agricultural Water Assessments**

Under the circumstance in which a grower *does* conduct the proposed agricultural water risk assessment, the use of recycled wastewater is, also, inadequately addressed in the proposed rule. In both § 112.43(a)(1) and FDA’s associated online Agricultural Water Assessment Builder<sup>2</sup>, when answering the question of the nature of the water source used, the only listed options are ground water or surface water, not recycled water.

Following this question regarding the nature of the water’s source, growers are asked to identify their level of control over the source of water, followed by the degree of protection from possible sources of contamination, including the presence of untreated or improperly treated human waste. The rule should ensure growers can clearly identify that they are utilizing recycled water under the written agricultural water risk assessment. **We therefore recommend the following adjustments to elements of the written agricultural water assessment:**

- **We recommend § 112.43(a)(1) be modified to read as follows [new text underlined]:** “Each agricultural water system you use for growing activities for the covered produce, including the location and nature of the water source (whether it is ground water, surface water, or recycled water furnished from publicly owned treatment works or public water systems), the type of water distribution system (for example, open or closed conveyance), and the degree of protection from possible sources of contamination (including by other water users; animal impacts; and adjacent and nearby land uses related to animal activity (for example, grazing or commercial animal feeding operations of any size), application of biological soil amendment(s) of animal origin, or presence of untreated or improperly treated human waste).”

Assuming this recommendation is adopted and that growers can denote municipally treated recycled water as their water source, **we recommend the following:**

- **FDA must clarify in the preamble to the final rule as well as in the Agricultural Water Assessment Builder and in subsequent guidance, that “untreated or improperly treated human waste” is not present in treated, recycled wastewater.** Water recycling includes the proper treatment of human waste in accordance with the Clean Water Act, state standards, and public health and environmental permits that set treatment levels based on the intended, planned use. Without additional guidance from FDA, a grower may

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<sup>2</sup> Food and Drug Administration. (2022). Agricultural Water Assessment Builder. Retrieved from <https://agwaterassessment.fda.gov/factors>

interpret using a recycled water source as inherently risky when specifically assessing the presence of improperly or untreated human waste.

Growers across the country reuse treated water sourced from municipal wastewater utilities to irrigate their farms, reduce the demand on potable water supplies, and increase the resilience of the water supply in their community. For decades, municipal wastewater has been treated and cleaned to protect human and environmental health in accordance with the Clean Water Act and with each state's regulations and guidelines, and to our knowledge, there have been no reports of food-borne disease attributable to the use of this water for produce irrigation.

Recycled water is often of higher quality with less degree of variability than water traditionally available to farmers, such as surface waters and groundwaters, which are exposed to a variety of pollution sources. There are 26 states currently with regulations allowing for the irrigation of food and non-food crops with recycled water that meets the microbial criteria threshold revision that we propose<sup>3</sup>.

Examples in California, Florida, and other states demonstrate growers partnering with their local wastewater utilities and state environmental and public health regulators to utilize treated municipal wastewater in a manner protective of human health. California and Florida are the two largest users of recycled water for produce irrigation in the United States. In the State of California, a rigorous agricultural reuse permit process exists through the State's Title 22 Code of Regulations, to ensure the safety of the water utilized on edible crops<sup>4</sup>. An extensive review of California's regulations for irrigation of food crops found current regulations adequately protected public health and that increasingly restrictive regulations would be unlikely to produce additional public health benefits<sup>5</sup>.

As the proposed rule stands, the burden of determining the level of risk associated with the reuse of treated municipal wastewater would fall to the grower. However, wastewater utilities providing treated, recycled water already comply with microbial criteria that is equivalent to or more stringent than the criteria of the 2015 produce safety rule, and therefore can provide growers with a reliable water quality test results or certificate of compliance to ensure the safety of this water supply.

Under the Clean Water Act, wastewater utilities must meet the standards set in their National Pollutant Elimination Discharge Permits, which include microbial criteria for generic E. coli based on the values established by the Environmental Protection Agency's Recreational Water Quality Criteria. Given that municipally sourced recycled water is already treated to meet public health and environmental standards before it reaches the grower, we recommend FDA establish a test

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<sup>3</sup> Thebo, Anne. (2021). Evaluating Economic and Environmental Benefits of Water Reuse for Agriculture. The Water Research Foundation, Project no. 4829.

<sup>4</sup> California State Water Boards. (2018). Regulations Related to Recycled Water.

[https://www.waterboards.ca.gov/drinking\\_water/certlic/drinkingwater/documents/lawbook/RWregulations\\_20181001.pdf](https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/lawbook/RWregulations_20181001.pdf)

<sup>5</sup> Sheikh, Bahman. (2019). Agricultural Use of Recycled Water: Impediments and Incentives. The Water Research Foundation, Project no. Reuse-15-08/4775.

result- or certificate-based exemption for treated, recycled wastewater that meets the microbial water quality criteria established in the 2015 rule.

Water reuse and recycling is an essential tool for improving water quality and enhancing the water resiliency of communities across the nation. The use of treated recycled water in produce farming has been practiced for decades, providing growers and communities with safe, sustainable water supplies, and safe, edible crops. By grounding its exemptions in the best available science, as outlined above, the FDA can ensure that the rule does not needlessly undermine safe, resilient water systems. By making the adjustments to the elements of the written agricultural water risk assessment, the FDA ensures growers choosing to conduct the assessment have the proper avenues to assess recycled water sourced from water and/or wastewater facilities.

Finally, we urge FDA to identify opportunities to partner with water associations, the scientific community, and federal agencies such as the U.S. Department of Agriculture and U.S. Environmental Protection Agency (EPA) to develop communications resources regarding the safety of recycled water for agricultural uses. At the federal level, this work should be coordinated through FDA's participation in the newly established Interagency Working Group on Water Reuse, which EPA is administering. WateReuse looks forward to partnering with you and the Interagency Working Group on this outreach effort. Thank you for considering these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Patricia L. Sinicropi', with a stylized flourish at the end.

Patricia L. Sinicropi, J.D.  
Executive Director