

Issue Summary – 2/22/21

Overall: Should the Harmonized Standard allow treated surface water to be used for produce washing?

3.2.2. - Water use SOPs address the microbial quality of water or ice that directly contacts the harvested crop or is used on food contact surfaces.

If water or ice directly contacts the harvested crop or is used on food contact surfaces, including in the field, as the final wash step prior to consumer packaging, or as a cooling aid in a consumer package, operation's water use SOP requires that water or ice when applied meets the microbial standards for drinking water, as defined by prevailing regulation. **Water may be treated (e.g., with chlorine) to achieve the microbial standards** or to prevent cross-contamination. Ice and water shall be sourced/manufactured, transported, and stored under sanitary conditions. Special considerations or variances may be appropriate for some crops, e.g. cranberries and watercress, where deliberate flooding of the field is part of production and harvest practices

Compounding questions:

- What is the prevailing regulation to meet the “microbial standards for drinking water”?
 - [EPA Surface Water Treatment Rules](#) – requires water systems to filter and disinfect surface water sources; focused on pathogens including viruses (4-log removal), *Giardia lamblia* (3-log removal), and *Cryptosporidium* (2-log removal)
 - [EPA Ground Water Rule](#) – focused on preventing illness from groundwater susceptibility to fecal contamination; requires a scientific basis for expecting at least 4-log virus inactivation that is verified by either continuous monitoring or daily grab samples; source water monitoring may be triggered by total coliform positive according to TCR
 - [EPA Total Coliform Rule](#) – monitoring requirements for public water systems to verify adequacy of water treatment and integrity of the distribution system; tiered sampling process first for TC, if (+), then follow-up with sampling for *E.coli*; requires assessments and corrective action if monitoring demonstrates potential for contamination. No more than 1 TC+ allowed monthly for systems taking <40 samples/month.
 - [National Primary Drinking Water Regulations](#) – compilation of all maximum contaminant levels (MCLs)
 - *Cryptosporidium*: Unfiltered systems are required to include *Cryptosporidium* in their existing watershed control provisions
 - *Giardia lamblia*: 99.9% removal/inactivation.
 - Viruses: 99.99% removal/inactivation.
 - *Legionella*: No limit, but EPA believes that if *Giardia* and viruses are removed/inactivated, according to the treatment techniques in the Surface Water Treatment Rule, *Legionella* will also be controlled.
 - Turbidity: For systems that use conventional or direct filtration, at no time can turbidity (cloudiness of water) go higher than 1 Nephelometric Turbidity Unit (NTU), and samples for turbidity must be less than or equal to 0.3 NTUs in at least 95 percent of the samples in any month. Systems that use filtration other than the conventional or direct filtration must follow state limits, which must include turbidity at no time exceeding 5 NTUs.
 - Heterotrophic Plate Count (HPC): No more than 500 bacterial colonies per milliliter.
- These rules are intended for public water treatment systems – can growers realistically meet these standards? From a risk standpoint, do they need to?
 - Filtration systems needed to remove parasites
 - **Original Produce Safety Rule Agricultural Water requirement for water used during and after harvest of covered produce (and food-contact surfaces including handwashing) is no detectable generic *E. coli*/100 mL water. Sampling frequency and allowed analysis methods are also specified.**
 - **PSR Ag Water rule also allows treatment of water to meet this standard (specifically, “...you must not use untreated surface water for any of these purposes...”)**

- How is surface water defined?
 - FDA - “all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water”
 - LGMA (also in Harmonized pre-harvest water assessment guide) - “Water either stored or conveyed on the surface and open to the environment. (e.g. rivers, lakes, streams, reservoirs, etc.)”
 - EPA – “water upon the surface of the earth, whether contained in bounds created naturally or artificially or diffused. Water from natural springs shall be classified as surface water when it exits from the spring onto the earth’s surface.”

If surface water is allowed to be treated for used in produce washing:

- Can the same antimicrobials use for produce washing be used for treating water?
 - Contact the chemical supplier for specific recommendations
 - Produce washwater antimicrobials are meant to be dosed in potable water; this is the generally the experimental framework that suppliers conduct their studies with
 - It’s unlikely the same label procedures can be followed to adequately treat surface water for the purposes of achieving a drinking water standard, though the supplier may have other antimicrobials available for this purpose (for bacterial and viral pathogens, not parasitic)
 - Water may need to be made ‘clean’ before treatment (filtration, ClO₂, O₃, etc.)
 - **Grower/packer should be able to provide some sort of verification that the correct chemical is being used, and that it’s being used properly** (label statement, letter from chemical supplier, etc.)
- Is there standard language that is expected on a label to consider it ‘approved for use’?
 - At a minimum, should include effectiveness against *E. coli* (either generic or O157:H7) and/or other public health organisms
 - Some chemical suppliers do offer antimicrobials with this type of statement (contrary to previous concern)
- What are the expectations for validation and/or verification that the treatment is effective?
 - Best practices is for growers/packers to NOT use surface water for produce washing
 - The calibration committee subgroup generally agreed that there is a **degree of acceptability** for growers to show effective treatment of surface water
 - E.g. if a grower tested their treated water to show non-detectable *E. coli* every time they used it, that would be ok
 - That is *NOT* the standard we want to set – should be determined on case-by-case basis; see following page for **risk assessment considerations**

Recommendations

- Harmonized Standard Calibration Committee should **not** prohibit outright the use of surface water for produce washing
 - For PSR covered growers – follow FDA Ag Water rule monitoring requirements for covered crops (final requirements may change based on upcoming proposed rule)
 - For growers not covered – follow risk assessment considerations on the following page and EPA Total Coliform rule for post-treatment postharvest water standard
- Harmonized Standard language/guidance should **not** specify water treatment validation or monitoring frequency, instead should be determined on case-by-case basis, based on considerations laid out on following page; as needed, committee can provide interpretation on specific audit scenarios as needed
- Highlight requirement 3.2.2. for review during next revision period – consider updating language to clarify “microbial standards for drinking water”.

Risk Assessment Considerations to Assess Surface Water Treatment for Postharvest Use

Treated surface water may be used as agricultural water for postharvest contact with fruits and vegetables, or food-contact surfaces (including hand washing), if risk assessment indicates that risk is sufficiently low.

- Source characteristics
 - Is the source surface or ground water (e.g., a well or spring)?
 - Following definition laid out in FDA's Produce Safety Rule
 - Is the water source entirely under the control of the user (e.g., from ground water source to a pool or from a rainwater catchment to a cistern, not a stream or river or other shared body of water)?
 - If not, has the user conducted a risk assessment that considers other factors that may negatively impact the water source microbiological quality?
 - Is the holding volume (e.g., pool or cistern) protected from impact by domesticated animals and wildlife (e.g., exclusion fencing to prevent domesticated animal access; diversion of first-flush rainwater to remove droppings-impacted water)
 - Can catchment system be cleaned/sanitized in the event of contamination?
 - Does the user have records indicating that the source is not subject to unexpected/ otherwise-unobserved contamination (e.g., a history of water tests showing concentration consistently below a benchmark such as 100 CFU or MPN/100 mL)
 - Is there reason to believe the microbial quality, physical characteristics, and/or risks associated with the water source varies by season? Has the user assessed this?
 - Does the user adequately control potential sources of contamination to water source?
- Label conditions
 - Is the chemical used registered by EPA as an antimicrobial pesticide?
 - Does the label support the use for treatment of water?
 - Does the label require a potable rinse after contact with treated water? (If so, this would not be an appropriate treatment)?
 - Does the label include an efficacy statement that indicates sufficient treatment level (e.g., 99.9% kill of generic *E. coli*) that is consistent with the water quality characteristic of the source (e.g., less than 100 CFU/100 mL) with a margin of error (e.g., in this example a factor of 10)?
- Treatment and Monitoring
 - Has testing been done on the water to support the physical and chemical characteristics (e.g., pH, turbidity, total dissolved solids as consistent with label statements about raw water characteristics) and microbiological characteristics for effective treatment?
 - This may include an initial validation as well as continuous monitoring before and/or after treatment
 - Does the user maintain records of effective treatment including, at a minimum, routine monitoring for active ingredient concentration during use along with any chemical characteristics that might change during use (e.g., pH)
 - Is the water treated in batches, or continuously in a system?
- Commodity characteristic
 - Does the product have an assumed kill-step completed by the consumer (i.e., is it rarely consumed raw)?