APPENDIX B:
TECHNICAL BASIS DOCUMENT FOR
COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE LETTUCE AND LEAFY GREENS SUPPLY CHAIN
~~2nd~~ *3rd EDITION*

~~April 18, 2007~~ August 25, 2015

- Existing test methods may not be able to detect the wide variety of pathogenic organisms that might contaminate water (World Health Organization 2004). Even if water is routinely tested for the more common pathogenic organisms, this does not guarantee other pathogens are not present.

Given the reasons above, and guidance and/or comments from various regulatory agencies (US EPA 1986; California Department of Health Services (CDHS) and California Department of Food and Agriculture (CDFA) 2006; US FDA 2006), use of an "indicator" microbe was determined to be the most effective and efficient testing approach. Testing for generic *E. coli* is considered the best available indicator of a fecal contaminated water source.

Generic *E. coli* is generally non-pathogenic; thus, using this as an indicator organism results in action levels that are not necessarily health risk-based. Although increasing levels of generic *E. coli* in a water source are likely to correlate with increasing health risk, "bright line" levels of generic *E. coli* above which health risks are unacceptable can not rationally be established. Action levels based on generic *E. coli* concentrations should not be considered as separating "safe" or "unsafe" levels—they should only be considered as indicators of fecal contamination or increasing bacteriological densities.

To set generic *E. coli* action levels for water used in agricultural applications, it was decided that it would not be possible to use one set of levels for all uses. For instance, water that contacts edible portions of plants should likely have more stringent standards than water that does not contact edible portions of plants. In order to address this issue, use-specific standards were created for three uses determined to be most critical to lettuce and leafy green food safety:

- Pre-harvest foliar applications. Where edible portions of the crop are contacted by water (e.g. overhead sprinkler irrigation, pesticides/fungicide application, etc.).

- Pre-harvest non-foliar applications. Where edible portions of the crop are not contacted by water (e.g., furrow or drip irrigation, dust abatement water).

- Hand Wash and Post-harvest water direct contact applications. (e.g. re-hydration, core in field, harvest equipment cleaning, bin cleaning, product cooling, product washing).

For each use category, a rolling average and single sample maximum metric was set. These metrics were based on water quality standards developed by the U.S. EPA in their risk assessment of *E. coli* in recreational waters were used to establish action levels (US EPA 1986;2003). U.S. EPA determined that the geometric mean of *E. coli* in recreational water systems should not exceed 126 MPN *E. coli*/ 100 mL to protect against unacceptable risk of waterborne diseases. In addition to this geometric mean value, they also determined single sample maximum values for various beach-use types. These single sample maximums are based on certain confidence levels of the geometric mean value of 126 MPN. For a "Designated Beach," U.S. EPA used the 70% confidence level, which is a value of 235 MPN/100 mL. For rarely used beaches, they used the 95% confidence level of 576 MPN/100 mL. These three guidelines were used to establish action levels for pre-harvest water uses. All pre-harvest water uses must meet the geometric mean requirement of 126 MPN/100 mL, but foliar applications must adhere to the lower 235 MPN/100 mL metric while non-foliar applications use the less strict 576 MPN/100 mL standard. The use of these values is