



## USApple Backgrounder

### Applying the FDA Revised Agricultural Water Proposals to the Orchard

In the FDA's revised rule proposals regarding agricultural water, the agency has significantly changed the original standards and testing requirements. The new proposal replaces the original requirement of weekly or monthly testing of water throughout growing season with microbial standards based on EPA "recreational water" standard. The revision calls for establishing a "baseline" for microbial presence in agricultural water using calculations of the geometric mean of Colony Forming Units (CFU's) and the Statistical Threshold Value (STV). The STV approximates the 90<sup>th</sup> percentile of the water quality distribution calculated from the results of samples tested.

Under the original rule proposal, growers would have been required to begin testing water at the beginning of the growing season and at intervals of 7 or 30 days depending upon the water source. **Worse**, if any of the tests exceeded the EPA recreational water standard, the use of water from that source would need to immediately cease until the problem was addressed.

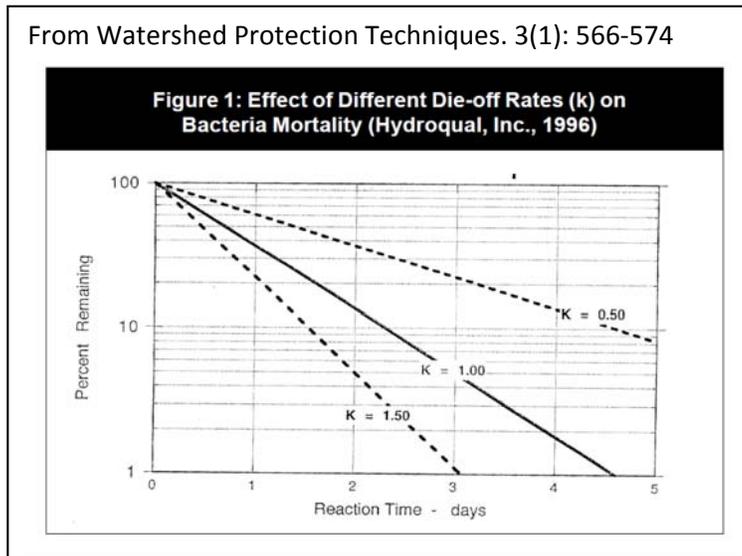
As noted earlier, under the new proposal, water testing will not be required throughout the growing season. After the establishment of a "baseline" calculated using a minimum of 20 samples collected as close to harvest as practical, growers will be required to collect and test 5 samples – once again, as close to harvest as practical. According to the FDA revised rule proposal (applying the EPA standard for recreational water), if the STV of samples exceeds 410 colony forming units (CFU) of generic E. coli per 100 mL of water, or if the geometric mean (GM) of samples exceeds 126 Colony Forming Units (CFU) of generic E. coli per 100 mL of water growers can:

- 1) Apply a time interval (in days) between last irrigation and harvest using a **microbial die-off rate of 0.5 log per day** (or an alternative microbial die-off rate consistent with paragraph (d)(2) of this section) to achieve a (calculated) log reduction of your geometric mean of generic E. coli level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 m, or;
- 2) Apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, or;
- 3) Immediately discontinue the use of that water source.

The FDA says in the revised proposals that it intends to develop a "tool" – most likely an "App" for cell phones or software to be installed on a laptop computer - that will assist growers in doing the mathematical calculations necessary to determine the interval between last water application and harvest, based upon the individual grower's water test results. Since the tool is

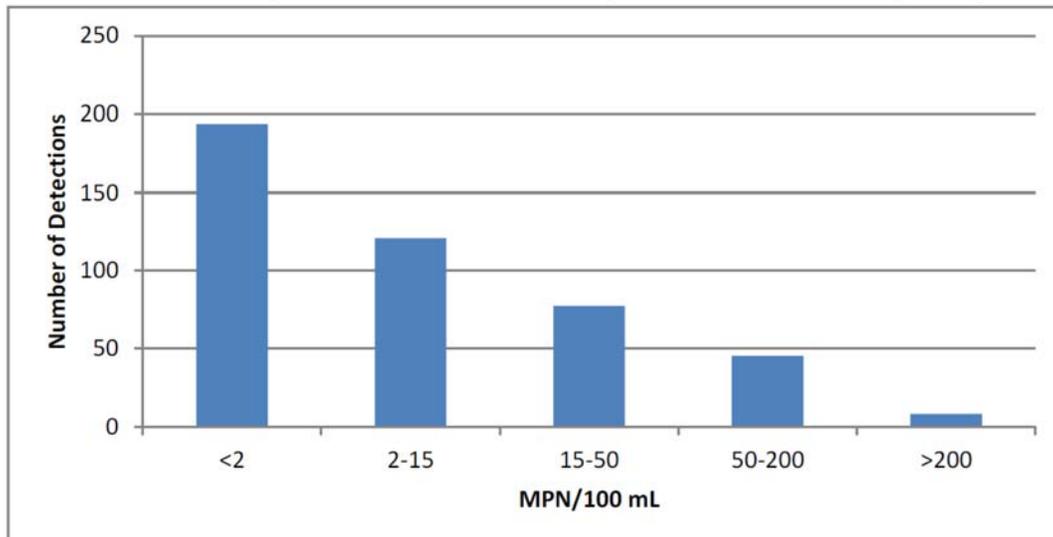
not yet available, in this example, we will do the calculations needed to determine the interval between last water application and harvest manually.

**Brief background** - Bacterial growth in the active phase occurs at an exponential rate. Conversely bacterial die off occurs at a rate expressed logarithmically. Figure 1 (next page) illustrates bacterial die off at the rates of log .5 ( $k=.5$ ), log 1( $k=1$ ), and log 1.5 ( $k=1.5$ ). At the die off rate of log .5, over 90 percent of the bacteria have died by the 5<sup>th</sup> day. **The FDA is allowing for the use of a die off rate of log .5 if other scientific studies of specific die off rates are not available.**



**The Orchard Example** – Over the time period from 2005-2012 the Center for Produce Safety (CPS) conducted a study of generic E. coli contamination of irrigation water from 17

FIGURE 1. Quantities of generic E. coli detected in irrigation water, 2005-2012 (N=445)



Washington State orchards. The industry microbial test results for generic E. coli in agricultural water during production ranged from <1 to 2,400 MPN/100 mL - 44% had levels less than 2 MPN/100 mL, 55% had levels between 2 and 200 MPN/100 mL, and 2% exceeded 110 MPN/100 mL (Figure 1 above). (**MPN –Most Probable Number** – is often used to describe the number of Colony Forming Units (CFU) per 100 ml water). While the majority of the samples tested were below the FDA standard of 126 CFU (or MPN)/100 ml, the test showed one sample out of 445 total samples with an MPN of 2400/100 ml – roughly 19 times the FDA standard of 126 CFU (or MPN)/100ml.

To simplify the calculation, and because the CPS study did not calculate the geometric mean or the STV for the samples taken, we will simply use the value of 2400/100 ml to calculate the number of days between last water application and harvest in this extreme case.

#### **Calculating the daily die-off**

- 1) MPN/100 ml remaining after Day 1 -  $(-\log .5)*2400 = \underline{722}\text{MPN(or CFU)/100ml}$  ( above the FDA 126 CFU/100ml standard)
- 2) MPN/100ml remaining after Day 2 –  $(-\log .5)*722 = \underline{217}\text{ MPN/100ml}$  (still above 126 CFU/100 ml )
- 3) MPN/100 ml remaining after Day 3 –  $(-\log .5)*217 = \underline{65}\text{ MPN/100 ml}$  (now below the 126 standard)

In the extreme case of water testing 19 times the FDA standard, the interval between last application of water and harvest is 3 days. In reality, only a very small number of samples tested in the CPS study even exceeded the FDA standard, so for the majority of test results, no interval between last water application and harvest would be necessary.

For more information, below is language lifted from the FDA’s revised agricultural water proposals that describes the agricultural water provisions and provides some additional examples of how to apply the standard and calculate the interval between water application and harvest.

#### **From the FDA revised produce food safety rules pages 68-70**

“First, you must conduct a baseline survey over a minimum period of 2 years to develop a water quality profile of your water source, based on which you would be able to determine whether the water meets the microbial quality requirements established in § 112.44(c). If it does not satisfy those requirements, then you must consider and implement any one of the options provided in §§ 112.44(c)(1), (c)(2), and (c)(3), as appropriate for your commodity and practices and conditions on your farm, if you wanted to continue to use the water source for the growing of produce (other than sprouts) using a direct water application method.

Second, every year after this initial baseline survey, you must conduct an annual survey to verify your water quality profile and ensure that the way in which you are using the water continues to be in accordance with § 112.44(c). If your annual survey verifies your water quality profile is still likely to be representative of the quality of your water source, no

additional steps would be necessary in that year. If, however, the annual survey results are sufficiently different from your existing water quality profile to suggest that the profile is no longer representative of the quality of your water source, you would be required to develop a new water quality profile and make adjustments to the way in which you are using the water in accordance with 112.44(c), as necessary.

**Baseline Survey**--For the baseline survey described in § 112.45(b)(1)(i) and (ii), we are proposing that the survey must be conducted over a minimum period of 2 years, by calculating the GM and STV values of generic E. coli (CFU per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest.

For example, if you determined (using the procedures described in proposed §§ 112.45(b) or 112.45(c), as applicable), that your agricultural water which is to be used for the purposes described in § 112.44(c) has generic E. coli levels with a GM value of 241 CFU per 100 mL and a STV value of 576 CFU per 100 mL, your water would not meet the microbial quality specified in § 112.44(c), in that your values exceed both the GM value of 126 CFU per 100 mL and STV value of 410 CFU or less per 100 ml. Under proposed § 112.44(c)(1), you would be able to use this water by applying a calculated time interval of 1 day between your last irrigation event (by direct application method) and harvest of the crop. Using a microbial reduction rate of 0.5 log per day, a 1-day time interval would be sufficient to meet the microbial quality requirements specified in § 112.44(c) because it would reduce your GM and STV values to 76 CFU per 100 mL and 182 CFU per 100 mL, respectively.

For example, in Year 1, Farm A conducts a baseline survey by taking 20 samples of its water source and testing them for generic E. coli, as described under § 112.45(b)(1)(i) and (ii), which indicates a GM of 125 CFU/100 mL and STV of 400 CFU/100 ml. This is the farm's initial water quality profile for this water source. The farm's GM and STV are below the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). Thus, based on this water quality profile, the farm would not be required to and does not implement any of the mitigation measures specified in §§ 112.44(c)(1) through (c)(3) in Year 1.

**Year 2** - In Year 2, Farm A conducts an annual survey by taking five samples of its water source and testing them for generic E. coli, as described in § 112.45(b)(2), and determines that the GM and STV values based on these five samples are 500 CFU/100 mL and 1600 CFU/100 mL, respectively. The farm finds that these Year 2 values are not consistent with the existing water quality profile because there is greater than a 0.5-log difference between the annual survey values and the water quality profile values. Therefore, as required by § 112.45(b)(2)(ii), the farm develops a new water quality profile. To do this, the farm uses its 5 test results from Year 2's annual survey, combined with 15 test results representing the most recently collected samples from the farm's earlier baseline data set to make up a data set of 20 samples, as described in § 112.45(b)(2)(ii)(A). The farm uses these 20 test results to develop a new water quality profile. The farm's new water quality profile GM and STV values are 200 CFU/100 mL and 600 CFU/100 mL, respectively. The farm's water quality profile GM and STV are now above

the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). As a result, as required by §§ 112.45(b)(2)(ii) and 112.44(c), the farm must either apply a time interval as a mitigation measure (§ 112.44(c)(1) or (2)) or discontinue using the water for direct water application during growing covered produce until the water meets the water quality standard (§ 112.44(c)(3)). A 1-day time interval between last water application and harvest (under § 112.44(c)(1)) would be sufficient to meet the microbial quality requirements specified in proposed § 112.44(c) because it results in calculated GM and STV values of 63 CFU/100 mL and 190 CFU/100 mL, respectively. The timing of the Year 2 crop cycle is such that the farm is able to develop its new water quality profile and take action prior to the end of the current harvesting season, and the farm chooses to apply a 1-day interval between last water application and harvest.

As another example, all of the circumstances for Farm B are the same for Farm A, except that Farm B's Year 2 annual survey test results are not available prior to the end of the current harvesting season. In this example, the farm would modify its practices in Year 3 based on the new water quality profile values developed in Year 2. Farm B chooses to apply a 1-day interval between last water application and harvest, as required under § 112.44(c)(1), during Year 3.

As another example, Farm C conducts a baseline survey by taking 20 samples of its water source and testing them for generic E. coli, as described under § 112.45(b)(1)(i) and (ii). Using these test results, the farm calculates a GM of 241 CFU/100 mL and STV of 576 CFU/100 mL. This is the farm's initial water quality profile for this water source. The farm's GM and STV are above the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). As a result, as required by §§ 112.45(b)(2)(ii) and 112.44(c), the farm must either apply a time interval as a mitigation measure (§ 112.44(c)(1) or (2)) or discontinue using the water for direct water application during growing of covered produce until the water meets the water quality standard (§ 112.44(c)(3)). The farm chooses to apply a one-day interval between last water application and harvest.

In Year 2, Farm C conducts an annual survey by taking five samples of its water source and testing them for generic E. coli, as described in § 112.45(b)(2). The farm calculates that the GM and STV values based on these five samples are 3000 CFU/100 mL and 5800 CFU/100 mL, respectively. The farm finds that these Year 2 values are not consistent with the existing water quality profile because there is greater than 1-log difference between the annual values and the water quality profile values. Therefore, as required by § 112.45(b)(2)(ii), the farm develops a new water quality profile. To do this, the farm uses its 5 test results from Year 2's annual survey, combined with 15 test results representing the most recently collected samples from the farm's earlier baseline data set to make a up a data set of 20 samples, as described in § 112.45(b)(2)(ii)(A). The farm uses these 20 test results to develop a new water quality profile. The farm's new water quality profile GM and STV values are 475 CFU/100 mL and 1050 CFU/100 mL, respectively. These values are different from the ones the farm used in Year 1 to calculate its time interval under § 112.44(c)(1). The farm must now use the Year 2 new water quality profile GM and STV values to reconsider and implement one of the mitigation measures specified in §§ 112.44(c)(1) through (c)(3). A 2-day time interval between last water application

and harvest would be sufficient to meet the microbial quality requirements specified in proposed § 112.44(c) because, using the Year 2 water quality profile values, a 2-day interval would result in calculated GM and STV values of 48 CFU/100 mL and 105 CFU/100 mL, respectively.”

***If you have any questions, please contact Mark Seetin, Director of Regulatory and Industry Affairs at (703) 442-8850 or email [mseetin@usapple.org](mailto:mseetin@usapple.org).***