How Did FDA Establish Requirements for Water Quality and Testing of Irrigation Water?

Questions and Answers with Samir Assar

Public comments submitted in response to the proposed Produce Safety Rule, both as originally proposed and as revised in the supplemental notice, indicated concerns about the complexity and cost of the new requirements for agricultural water.

Samir Assar, Ph.D., director of the Division of Produce Safety, addresses those concerns and explains the FDA's reasons for establishing the water quality and testing provisions outlined in the final rule. He focuses on the requirements for water that directly contacts growing produce, other than sprouts (which have a more strict standard for irrigation-water quality).

■ **Q: Some challenge the scientific basis of the microbial water quality criteria, saying that generic *E. coli* is not appropriate for use in assessing the safety of agricultural water used for any purpose. And they question the use of Environmental Protection Agency (EPA) criteria for recreational water as a basis for the criteria for water that directly contacts growing produce (other than sprouts) in the final rule. What scientific support was used to craft the final standards?**

The types of water used for agricultural water are incredibly diverse. After reviewing scientific literature, we determined that generic *E. coli*, bacteria found in the intestinal tract of both people and animals, are consistent indicators of the presence of feces.

Identifying fecal contamination is important in assessing the safety of agricultural water. As such contamination increases, so does the likelihood that disease-causing microorganisms are also present.

The science behind EPA's recreational water criteria is based on recent epidemiological studies, and the scientific evidence showed that people have gotten sick by swallowing recreational water that is contaminated with feces. Using these criteria as a starting point, we took into consideration other technical information and recommendations to account for circumstances unique to produce growing. For example, we analyzed guidelines issued by the World Health Organization, which helped shape our provisions for post-irrigation microbial die-off and microbial removal.

Overall, this rule (including our water quality requirements) has a strong foundation in science and the risks associated with production practices.

■ **Q: Is it necessary to use two different numerical criteria for water that directly contacts growing produce (other than sprouts), both the geometric mean (GM) and statistical threshold value (STV)? Does this need to be so complex?**

The criteria are complex because the nature of agricultural water is complex. It's important to keep in mind that agricultural water is estimated to be the most important pathway of contamination.

The goal of these water quality criteria is to understand and describe water sources and water distribution systems. For untreated water used for this purpose, the required criteria are a GM of samples of 126 CFU or less of generic *E.coli* per 100 mL of water, and an STV of 410 CFU or less of generic *E.coli* in 100 mL of water. (CFU stands for colony forming units, a measure of bacteria.)

Why are there two criteria for this water use? Because the GM and STV capture two different pieces of information about the distribution of levels of generic *E. coli* in a water source. The geometric mean (GM) measures what is called the central tendency, which is essentially the average amount of generic *E. coli* in a water source. The STV reflects the amount of variation in the *E. coli* levels, which can be caused by events such as a heavy rainfall. It measures expected deviations from the average for a water source. Collectively, both pieces of information provide a more complete description of your water quality than either one alone.

Accounting for the variability of *E. coli* levels in water sources also makes make it much less likely that a farm will have to discontinue use of its water source due to small fluctuations in water quality.

Q: Are these water quality criteria absolute or has some flexibility been provided?

There is quite a bit of flexibility provided in the final rule. Even if their water initially exceeds the GM/STV criteria for water that directly contacts growing produce (except for sprouts), farms do not have to immediately discontinue use of the water used for this purpose. The rule allows farms to take corrective measures as soon as practicable, but no later than the following year, to achieve the microbial quality criteria. Options for corrective measures include:

- Applying a specific amount of time (in days) between last irrigation and harvest (up to a maximum four days), and/or between harvest and end of storage to allow time for potentially dangerous microorganisms to die off. Farms could also apply a calculated log reduction during activities such as commercial washing. (A log reduction estimates how many live bacteria will be eliminated by the activity.)
- Re-inspecting the entire affected agricultural water system under the farm's control and, among other steps, making changes to ensure that its water meets the criteria.
- Treating the water.

Farms can also use alternative water quality criteria, using a different indicator organism for fecal contamination (instead of generic *E. coli*) or different numerical criteria (instead of the GM and STV). A farm could also use a different microbial die-off rate and accompanying maximum time interval. FDA does not have to approve these alternatives, but farms must have adequate scientific data and information to support their conclusion that their alternatives provide the same level of public health protection as is provided by the final rule, and do not increase the likelihood that the produce will be unsafe or otherwise adulterated.

An important source of such information is peer-reviewed scientific literature. Farms might also use the results of third-party testing, or data derived from their own operation. Scientific support may come from commodity-specific or other guidance developed by FDA, industry, academia, trade associations, or other stakeholders. Combining information from peer-reviewed, scientific literature with other data and resources would help provide a robust support for an alternative approach.

These options provide significant flexibility for compliance with the rule and can account for potential differences among regions, commodities and farming practices. Farmers will not have to figure out on their own how to justify alternative approaches. FDA will be issuing a guidance document to help farms understand the use of alternatives.

Q: What do you say to commenters who complained about the proposed water-testing regimen? They called the number of required samples excessive and costly.

We recognize the range of water uses on farms. The final rule provides a framework to ensure that farms (and inspectors) know what is expected, but it also provides enough flexibility to deal with the incredible variations in water use for different foods, regions and practices.

We have established different testing regimens for untreated surface and ground water. More sampling is required for surface water because it is far more vulnerable to contamination than ground water and therefore greater variability in generic *E. coli* levels is expected.

- Surface water testing will require a minimum of 20 initial samples collected over two to four years. After that, farms must test a minimum of five samples a year. The microbial water quality profile will thus be updated annually on a rolling basis using a minimum of 20 samples. The calculation of the GM and STV will typically be based on the five new samples and 15 of the most recent earlier samples.

- Ground water testing will require a minimum of four initial samples over one year, followed by a minimum of one new sample each year. The profile will be updated annually using at a minimum the most recent four samples.

These are the minimum numbers of samples we consider statistically necessary to provide a picture of the surface and ground water quality.

There are a number of factors in the final rule that we expect will reduce testing frequency and cost. These considerations include:

- The GM/STV criteria, and the associated testing requirements, do not apply to water that does not come in direct contact with the harvestable portion of the produce. For example, these requirements will not apply to water used for drip irrigation of tree crops that grow high above the ground and are not likely to touch the ground.

- Farms that use a public water system or supply will not have to test their water, provided that there are documents establishing that the public water meets specific criteria.

- Farms can utilize data obtained from other parties, as long as the samples tested adequately reflect the farm's water source and all other applicable requirements of the rule are met. For example, other requirements include the timing of the collection of samples and the number of samples collected.

- Alternatives to the minimum number of samples for the initial or annual survey can be developed, as long as it is established that the alternative approach provides the same level of public health protection as the testing frequency established in the rule and does not increase the likelihood that the produce will be unsafe or otherwise adulterated.

- Variances can also be requested by state, tribal and foreign governments, with supporting information to justify use of a different approach that is appropriate based on factors that may include the crop, climate, soil or environmental conditions of a region. While variance requests are limited to those submitted by government regulatory authorities, FDA anticipates that in many cases, industry groups and other stakeholders will be working with these government entities. Industry groups and other stakeholders could, for example, develop the scientific data necessary for a state, tribal, or foreign government's variance request.

We intend to work with farms by issuing a guidance document outlining these considerations, including utilizing alternatives and variances.

We believe that the cost of testing is justified based on the significant risk that agricultural water poses as a source of contamination and foodborne illness. FDA estimates that agricultural water provisions, as written in the final rule, will cost approximately $37 million dollars annually, which represents an average cost to a single farm of approximately $1,058 per year.

The agency anticipates the final rule will bring about a reduction of over 60 percent in the risk of contamination from agricultural water, or a reduction of about 20 percent in the total number of foodborne illnesses associated with produce, with a corresponding reduction of $477 million in the costs of foodborne illnesses.

- **Q: How will FDA be helping farmers understand the new water quality and testing requirements, including how to calculate the GM and STV?**

For the microbial water quality criteria, we understand that calculations associated with the GM and STV values are complicated. We are working to develop online tools to help farms with these calculations. We will continue to work with educational organizations and partners to develop resources to assist farms.

FDA recently issued a training strategy in which we outline plans to work with public and private partners providing training for farms, both small and large.

We will also be working with cooperative extension, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms. This is in addition to establishing a Food Safety Technical Assistance Network to provide a central source of information to stakeholders.

There will be ample time for farmers to come into compliance. Compliance dates are staggered according to the size of the business, with an extra two years being provided to meet some of the agricultural water requirements for most farms. The result is (for produce other than sprouts) compliance periods of six years for very small farms, five years for small farms, and four years for all other covered farms for certain water provisions.

The bottom line message is: You're not in this alone. FDA will continue to provide guidance and information about the water provisions and will work with our partners to provide the resources and tools needed to understand and meet these requirements. ■