CAFF: Discussion of FDA Produce Rule—Water

Background on the Rule

There is no doubt that water is one of the principal mechanisms through which produce has become contaminated with pathogens, whether through the application of contaminated irrigation water or contaminated wash water.

Definition of Agricultural water: water used in covered activities on covered produce, where water is likely to contact covered produce.

- Direct contact Irrigation water
- Crop spraying
- Washing and cooling of covered produce
- Cleaning food contact surfaces
- Hands during and after harvest activities

Water must be safe and sanitary for its intended use

- Overhead Irrigation : 235 CFU generic *E. coli* per 100ml (direct contact with covered produce)
- Harvesting operations: 0 detectable generic *E. coli* (Dump tanks, cooling, ice, flumes, hydro-coolers--highest risk uses; packing sheds)
- Hand Washing: 0 detectable generic *E. coli*
- Buried Drip Irrigation : Not Ag water as defined by FSMA (Subject to FD& C act)

Testing Requirements

- Public Water System: No Testing
- Private Well: Every 3 months
- Rivers or natural lakes: once every 7 days
    - If you want to water your crops with overhead irrigation—or any form of irrigation that will come into contact with the crop—from a pond, stream or river, you will test that water at least once per week, per source, throughout the growing season.
- On-farm man-made reservoir: monthly if not subject to run off, otherwise weekly

If you want to do something different show us a science-based alternative (FDA will not review just tell us you have it)

States may request exemptions based on regional conditions.

Likely consequences:

- More drip irrigation
- Water treatment systems
- Waste water disposal (from all that packing shed discharge)
- Pond maintenance

Issues

- Most surface waters of the United States will fail the proposed generic *E. coli* tests, at least periodically, which would imply a huge disruption to agriculture
    - Managers of irrigation districts tell us that surface water flowing into their districts will frequently fail the proposed standards. If there is no alternative source of water available to farmers in an area, the FDA is making it almost impossible to grow the covered commodities, even if no outbreak of foodborne illness has ever been traced to the area.
    - The level of concern is too low. If we go with this generic E. coli test, the point at which you stop and check should be raised from 235 to 500 or 1,000 cfu.
    - Some background level of generic E. coli should be established in each region. What is of concern are spikes in the level, not this background contamination coming downstream.
- Generic *E. coli* not correlated with pathogenic *E. coli*
    - Although a generic *E. coli* test is relatively inexpensive, it is a poor proxy for what is really being sought, namely the pathogenic E. coli, Salmonella, etc. Because of the poor correlation, such testing is more public relations than science.
- Weekly frequency of testing of surface water not justified with any quantification of risk, a huge waste of time and money
    - You could test hourly and the water would still be changing.
    - What if you test for years and never find any contamination? Why should every region be treated the same?
    - Testing monthly or even every 6 months probably sufficient unless some high level of contamination found. Could propose to test monthly for a year or two and then every 6 months if no spikes. The FDA proposal to test ground water quarterly and if no problems then annually is exactly the type of approach that should be taken.
    - There are no alternatives allowed for in testing frequency!
    - The frequency of testing should be moved to guidance as there is no scientific justification for testing water (especially surface waters) at any specific periodic interval.
    - The regulation should follow the HAACP Principles and be outcome based on risk assessment. In the preamble to the Produce Rule the FDA writes: "we agree that the frequency should reflect the risk. In proposed §112.45(a), with certain exceptions, we propose to require you to test water for certain purposes at the beginning of each growing season, and every three months thereafter during the growing season. We tentatively conclude that this frequency would provide sufficient information regarding the microbial quality of your agricultural water." It should have been left at that without the exceptions.
- Testing more costly in many places than FDA believes
    - FDA estimates the cost per test at $87. If you tested weekly for 9 months, that would be over $3,000 just for these tests that don't really tell you if there are any pathogens or not.
    - Farmers in remote areas will have trouble getting the samples to a lab in a timely fashion and it will be costly. Farmers in Hawaii said that there are no labs on most islands, so samples must be flown over to the lab, at a cost above $100 per test.

    - In New England costs of tests run from $25-50 per 100 ml sample. Surface water samples must be tested within 24hours of sampling and this may pose a challenge for those in rural areas or those not close to a lab.
- Encouraging the use of groundwater, but:
    - In some areas there is no groundwater
    - In some regions the groundwater is laden with salts, boron, magnesium, selenium and other substances that make it a poor or infeasible choice for irrigating crops
        - The Hollister region in California is an example of an area where surface water was brought in because the groundwater was so high in boron
    - In many regions groundwater is overdrafted and this will worsen the situation, creating a significant environmental impact
        - The southern San Joaquin Valley in California is an example of a region that has significantly overdrafted groundwater. The Central Valley Project and the State Water Project were in part created in order to bring surface water to the region so that farmers could stop overdrafting groundwater.
    - In regions with gravity surface irrigation, shifting to groundwater will increase energy use
    - The risk assessment should be farm based, not source of water based. All ground water is not equal and does not all merit monthly testing.
- Treatment of irrigation water infeasible
    - Apparently no approved treatments for irrigation water. Currently nothing approved by EPA under FIFRA for use in the field. There is not even an EPA process for considering which chemicals could be approved.
    - Several products approved for post-harvest operations: Bio Safe, Tsunami, Oxi-Date, chlorine, hydrogen peroxide and others for both organic and conventional farms. Increased use of antimicrobials will increase farm operating costs and may lead to capital costs to mitigate increased contaminated waste water discharges.
    - Significant environmental concerns are raised as a result of increased use of chlorine and or other antimicrobial pesticides into the environment. Pack shed discharge alone may create significant impacts on downstream water quality.
    - Treatment of large quantities of irrigation water is impractical, costly, and of dubious value. What is the point of killing generic E. coli when they are not the problem? Also, it has been shown that chlorine will not necessarily kill the pathogenic bacteria, and so treating the water might be achieving nothing other than driving up costs and contaminating the environment.
    - Treatment of water should be one option available to the farmer if he believes the water is abnormally contaminated, and this should be based on local experience and his individual risk assessment, not on some arbitrary number of generic E. coli.
    - The farmer should at the very least be able to cut off irrigation at a point prior to harvest as an alternative.
- Buried drip only feasible on certain crops
    - Pressurizing water will increase energy use
    - Drip is an added cost to producers and while appropriate for many crops and conserving of water resources does not work for all, is impractical on large

operations, certainly has its own environmental impact (disposable plastic product) and offers no frost protection.

- Regulating wrong entity, farmers not in control of water quality
    - If the surface waters of the United States are too contaminated to use for growing produce, wouldn't it make more sense to ask the EPA and the states to clean them up?
    - Animal feeding operations are constantly injecting pathogens into the environment, yet the FDA is not proposing to stop that.
- Wash water
    - Since the water used to wash produce is the most likely to contaminate it, the most attention should be paid to this water. The evidence indicates that fresh, clean water is as effective as water with chlorine or other chemicals in removing pathogens. Therefore encouraging farmers to use clean water and change it often would seem to be the best advice.
- The most important water issues are probably: direct application to above ground edible produce, the last irrigations before and at harvest, and cosmetic washing; also "incidental" water used for pesticide and other direct applications, and probably dust control water -- contributors to hazard or safety that often are not seen as part of the safety chain.
- Sometimes the best indicator would be a turbidity monitor, so when your irrigation district stirs up stuff along the ditches by dredging or fixing dams etc. you know to shut down (if you can).
- You can probably manipulate 5-6 logs of difference in the results of water tests by how and when you sample, so this is something to consider if the rule goes forward as it is.

Some Final Thoughts

The FDA, in the preamble to the Produce Rule, notes that comments received prior to writing this rule "supported a food safety system, grounded in science, for the production of produce in a fair and equitable manner for the domestic and imports. Comments noted that regulations developed should be science-based and provide for producers to manage risks in a manner appropriate to their operations."

However, the water rules are neither science-based nor do they allow farmers to judge the risks of their own operations. The issue is really who determines what is "safe and of adequate sanitary quality." The FDA wants to establish numerical standards of dubious validity and apply them to every farm in the world.

There is no science to support the use of generic E. coli at recreational water standards levels as an appropriate test for food pathogens.

The OTA comments are correct in pointing out that FDA's proposed testing and treatment requirements imply that "FDA has essentially already conducted the risk assessment for the industry and is proposing a blanket requirement to all operations across the country regardless of their risk level." But of course FDA has not conducted a risk assessment on every farm in the country, they do not have the data.

They write “Practices used for one region or commodity may not be appropriate for others based upon historical experience.” (p. 210 preamble)

Sure, States can request exemptions from this part of the rule based on past experience that irrigation water with high generic E. coli counts has not caused food safety problems with the produce being grown. But why write a rule that requires every state in the country to seek exemptions?

And since FDA has not quantified the risk of using surface water on crop A in region B, they are requiring measures that presume that the risk is significant, even though there may be no historical evidence that the risk is significant. This caused the Idaho onion growers to comment that they would no longer be able to grow onions if this rule went forward as is, even though there has never been a case of bulb onions making anyone ill.