

FSMA Facts

More on the Proposed Agricultural Water Standards – FDA’s Proposed Rule for Produce Safety

Background

FDA’s proposed rule for Produce Safety has as its foundation some of the important principles in the 1998 FDA Good Agricultural Practices (GAPs) Guide and other guidance developed in recent years by FDA and others to support safe growing and handling practices. This includes its focus on five main recognized routes of contamination for produce and its proposed requirements to prevent or reduce the introduction of pathogens to covered produce through these routes of contamination. Agricultural water is one of those. Agricultural water is a known on-farm route of produce contamination, and can be both a potential source of contamination and a means by which contamination can be spread.

FDA’s proposed requirements for agricultural water outlined in the proposed produce safety rule draw upon good agricultural practices being employed by farms following standards of the California and Arizona Leafy Greens Marketing Agreement, and several state produce safety programs, such as the Tomato GAPs (T-GAP) adopted several years ago by both field and greenhouse growers in Florida. The proposal is intended to reflect best practices that many farms already employ, while taking full account of the great diversity of growing conditions and practices and the need for rules that are adaptable to this diversity and make a practical difference for food safety.

FDA acknowledges that there are numerous water sources available to farmers, including ground water sources like wells, and different surface water sources like ponds, rivers, creeks, and canals. There are also municipal and water district supplies. FDA is also aware that there are upstream land and water uses that are beyond the control of growers that may

affect the quality and availability of their water; and that in some areas of the country, the choices of agricultural water sources are often limited. And finally, FDA acknowledges that how and when water is applied on the farm depends on the type of crops being grown.

In the proposal, we’ve tried to be flexible, and have tailored the stringency of the agricultural water requirements to the risk associated with water sources, along with how and when the water is actually used or applied. It is also important to keep in mind that this is a proposed rule. Once comments are received, FDA will need to analyze and assess those comments before a final rule is put forward.

Finally, agricultural water is one of the sections of the proposed rule for which FDA would allow for alternatives to certain specified requirements – essentially, allowing farmers to be in compliance without following certain specific standards that are outlined in the proposal if there is scientific evidence supporting the use of the farmers’ alternative approaches. FDA conferred with USDA (including the National Organic Program and the Natural Resources Conservation Service), EPA, the U.S. Fish and Wildlife Service, and others to take into consideration conservation and environmental practice standards and policies established by those agencies.

FDA understands that there are some strengths as well as limitations to our proposed rule. For the proposed agricultural water standards, as for all aspects of this proposed rule, FDA needs your comments and input. This is your opportunity to help shape the rules that will apply to your operations. The comment period has been extended until November 15, 2013.

More on the Proposed Agricultural Water Standards – FDA’s Proposed Rule for Produce Safety

You can go to the FDA FSMA web page for more information, www.fda.gov/fsma or go to www.regulations.gov to comment.

Summary of Some of the Key Proposed Requirements under Subpart E: Agricultural Water

The basic requirement is that all agricultural water must be safe and of adequate sanitary quality for its intended use. Under this proposal, agricultural water is defined as water used in activities on produce (covered under this proposal) where it is intended to, or is likely to, contact either the produce itself or surfaces that come into contact with the produce (food-contact surfaces), including water used in:

- growing, including:
 - irrigation water directly applied,
 - preparing crop sprays, and
 - growing sprouts
- harvesting, packing, and holding, including:
 - washing or cooling produce, and
 - preventing dehydration

The definition of agricultural water does **not** include indirect water application methods utilized during growing activities (i.e., water that is not intended to, or is not likely to, contact produce that is covered by the rule** or food-contact surfaces), such as furrow irrigation of fruit-bearing trees. A discussion of produce covered under the proposed rule (covered produce) is on page 4.

Assessment/Inspection of the Water System/Testing Frequency

FDA is proposing that growers inspect their water source(s) and distribution systems at the beginning of the growing season. We’re also proposing you regularly inspect and maintain any water sources that are under your control as well as your distribution system(s) so they do not become sources of contamination.

Testing agricultural water would be required when it is

used for certain specified purposes. Testing would be required for agricultural water applied to covered produce when it:

- is used to make treated agricultural teas,
- directly contacts the harvestable portion of the crop prior to harvest, or during or after harvest;
- directly contacts food-contact surfaces,
- is used for hand washing during and after harvest, and
- is used for sprout irrigation water

Farmers using public water systems or other water supplies under certain specified conditions, or for farmers who treat their water in accordance with the proposed rule’s treatment provisions would **not** be required to test their water. Certain actions would also need to be taken if a farm has reason to believe that its agricultural water is not safe and not of adequate sanitary quality for its intended use.

Testing Frequency

In proposing testing frequencies, FDA divided untreated surface water into two categories based on their potential to be impacted by runoff and the amount of control and protection that can be provided by the farm.

- Water that is susceptible to a significant amount of runoff, for example:
 - Flowing surface waters (rivers, streams, or creeks) or
 - natural ponds, lakes
- Water where runoff drainage is minimized, for example:
 - where underground aquifer water is transferred to a surface water containment such as an on-farm constructed water reservoir.

Surface water sources in the first category are susceptible to relatively rapid changes in water quality due to the many additional external forces shaping their composition. Thus a higher frequency of testing is proposed for these water sources than for the second category.

More on the Proposed Agricultural Water Standards – FDA’s Proposed Rule for Produce Safety

The proposed rule would also establish testing intervals for other water sources, such as ground water, that would be less frequent than the untreated surface water testing intervals. FDA sought to present practical intervals for water testing in the proposed rule. We welcome comments on the need for testing, and the proposed testing frequencies, including any alternative approaches and examples where testing should be more or less frequent based on your experience or observations.

Standards for Testing

FDA is trying to make sure that farms are assessing the quality of their water with respect to its intended use. We’re doing that by proposing two numerical standards. (see diagram)

1. No detectible *E. coli* present per 100 ml of water. This standard applies when you’re using water, including ice made from that water, for an activity both during and after harvest when there is a higher likelihood that pathogens would survive. For example, this standard would apply for uses in which there is normally a short time between application of the water and consumption of the produce (wash water, water used for hand washing, and water that touches food-contact surfaces). This standard also applies to sprout irrigation water and to water used to make treated agricultural teas because both uses are likely to allow pathogens to grow if they are present in the water.
2. No more than 235 colony forming units (CFU) generic *E. coli* per 100 ml for any single water sample and a rolling geometric mean (of five samples) of no more than 126 CFU/100 ml.

This standard applies to water used during growing produce covered by the proposed rule (other than sprouts) when it is applied in a manner that results in direct contact with the harvestable portion of the crop (for example, water used to apply pesticides or fungicides directly to tree fruit, or water used to irrigate crops by overhead spray after the

harvestable portion of the crop (for example, water used to apply pesticides or fungicides directly to tree fruit, or water used to irrigate crops by overhead spray after the harvestable portion is established) or food-contact surfaces.

In either case, if you find there is more generic *E. coli* than the numerical standard prescribes, you would be required to immediately discontinue use of that source for the use subject to the standard and take specific follow-up actions, including visually re-inspecting the water source and distribution systems, making changes to the system and re-testing; or treating the water.

Farms could also use the same water source for uses without numerical standards or for a use subject to a different numerical standard that the water satisfies. For example, a farm could use water that does not meet the non-detectible *E. coli* standard but does meet the 235 CFU/100 ml standard for direct application method irrigation of covered produce other than sprouts; or use water that does not meet the 235 CFU/100 ml standard for irrigation of covered produce other than sprouts in a way that is not a direct application method (such as furrow irrigation of fruit bearing trees). Exceeding the numerical standards would *not* necessarily mean that produce you already applied the water to is contaminated, but it would indicate that there is reason for concern about your water source or how it’s delivered with respect to the intended use of the water.

Treatment to Reduce Microbial Levels

Because agricultural water is used in many different ways on the farm, treatment of water (to reduce microbial levels) as a preventive control is not always necessary or warranted. The proposed basic standard for water is that it has to be safe and of adequate sanitary quality for its intended use. If you have reason to believe that the water is not safe and of adequate sanitary quality for its intended use, FDA is not proposing treatment of water as the only option.

More on the Proposed Agricultural Water Standards – FDA’s Proposed Rule for Produce Safety

The proposed rule would also permit farms to make necessary changes, and to retest the water to determine if those changes were effective and to ensure that the water is safe and of adequate sanitary quality for its intended use.

FDA is not proposing wholesale treatment of all agricultural water before it enters the farm or even before the farmer has considered its adequacy and safety for the uses for which it is intended.

Alternatives to the Water Testing Requirements

The proposed rule would permit you to use alternatives to requirements for testing water and taking action based on those test results when agricultural water is used during growing of produce covered by the rule (other than sprouts) using a direct water application method. To use an alternative you would be required to have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection and would not increase the likelihood that your produce would be adulterated under the Food Drug and Cosmetic Act.

Farmers would not need to ask FDA if they can use such alternatives, provided they have documented adequate scientific data and information to support an alternative. That documentation could be as simple as a peer-reviewed journal article or a State Extension bulletin, as long as it is science-based.

Recordkeeping

FDA is proposing that growers be required to maintain certain records, including:

- documentation of your findings from the inspection of the agricultural water system under your control;
- scientific data or information relied on to support the adequacy of water treatment methods; treatment monitoring results;
- water testing results;
- scientific data or information you relied on to support any alternatives to requirements, and

- certain documentation from public water sources, if used.

FDA has tried to keep the recordkeeping burden to a minimum. FDA seeks comment on these proposed recordkeeping requirements.

Extended Compliance Dates

FDA is proposing to delay implementation of certain provisions, including the water quality testing requirements, well beyond the effective dates for other provisions of the final produce rule. The proposed extended compliance dates for the water quality testing, monitoring, and related recordkeeping requirements are:

- Six years from the effective date (of the final rule) for very small businesses
- Five years from the effective date for small businesses
- Four years from the effective date for all other farms subject to the rule.

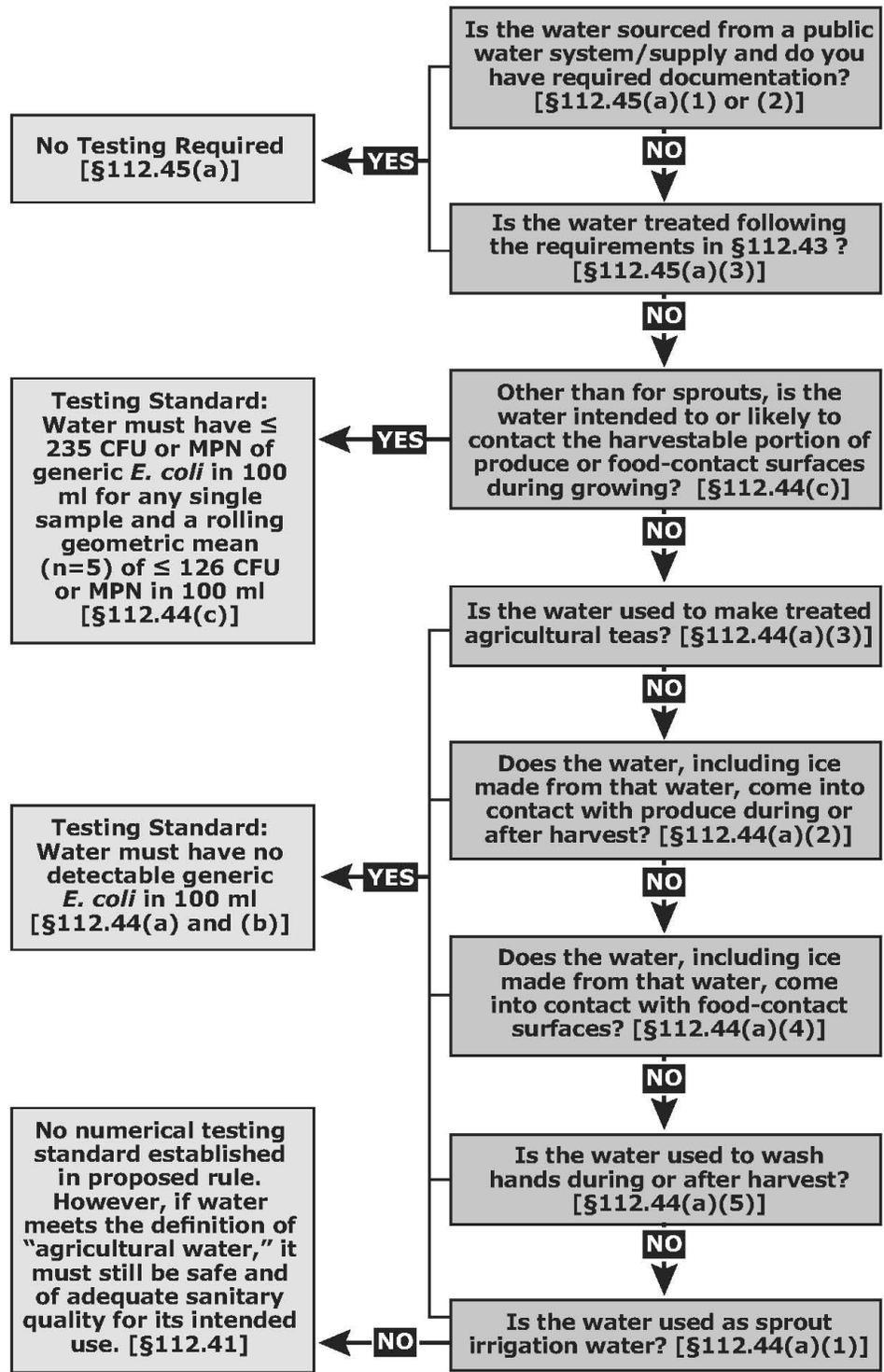
We expect these extended compliance dates to provide adequate time for industry to address issues related to agricultural water and to close some of the research gaps that exist in this area. FDA welcomes comments on this extended compliance schedule and all provisions proposed.

******The proposed rule would define “produce” to mean any fruit or vegetable (including mixes of fruits and vegetables) and includes mushrooms, sprouts (irrespective of the seed source), peanuts, tree nuts and herbs. Produce, in this context, does **not** include food grains, meaning the small hard fruits or seeds that are grown and processed for use as meal, flour, baked goods, cereals and oils. That means cereal grains, like wheat and corn are **not** covered by this rule. In addition, the proposed rule excludes certain commodities based on risk, that is, those that are rarely consumed raw (such as potatoes), and produce that will receive commercial processing that adequately reduces the presence of microorganisms of public health significance (such as low acid canned foods). The proposed rule would also not apply to produce grown for personal or on-farm consumption.

Updated: 8/9/13

More on the Proposed Agricultural Water Standards – FDA’s Proposed Rule for Produce Safety

Agricultural Water - Proposed Numerical Testing Standards and Exceptions



References/citations on this diagram are to sections of the Proposed Produce Rule <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm350787.htm>
 U.S. Food and Drug Administration 2013