

Contact:
 Amanda Bryant
 Director, Communications
 (202) 296-9680
amanda@nasda.org

FOR IMMEDIATE RELEASE
 September 20, 2013

State Agricultural Officials Encourage Congressional Action on Food Safety Rules

At the annual meeting of the National Association of State Departments of Agriculture (NASDA), state agricultural officials from around the country reaffirmed their support of the goals of the Food Safety Modernization Act (FSMA) and voted unanimously to go to Congress and the Food and Drug Administration (FDA) to assure adequate due process for the promulgation of FSMA rules.

NASDA supports the implementation of a food safety program and believes Congress should allow FDA to postpone finalization of this set of rules until a second draft of proposed rules can be published for public input.

NASDA members recognize the need to act swiftly to implement the law, which includes rules governing Produce Safety, Preventive Controls, Animal Feed, Import, and Third-Party Verification. However, given the complexity of the proposed rules, the current timeline may not allow FDA to craft a sound and operable food safety program.

Oregon Director of Agriculture Katy Coba, Chair of NASDA's Food Regulation and Nutrition Committee, said, "Since FDA's release of the rules earlier this year, NASDA members have been working diligently to review this necessary overhaul of America's food safety regulatory system, but it is imperative we get this right. These rules must be workable for agriculture and reflect the realities of food production"

"I am learning from conversations with my fellow NASDA members that they too are concerned about the ability to enforce rules that are unclear," said Coba. "Growers in my state are concerned about the complexity of following multiple rules and feel some alternatives might be a better way to proactively regulate certain commodities. We want to work with FDA and other stakeholders to get the rules right."

One of the many reasons FSMA was passed was to level the field between domestic and foreign producers. NASDA members expressed concern they are hearing from producers regarding their fears that enforcement of domestic growers will be greater than imported food producers.

North Carolina Commissioner of Agriculture Steve Troxler, NASDA President, hosted NASDA members in Asheville, North Carolina. As the chief regulator of North Carolina's 52,000 farms, Troxler knows first-hand the importance of ensuring these proposed food safety rules provide a common sense framework for an integrated state-federal implementation of FSMA.

"We have appreciated FDA's willingness to meet one-on-one to hear many state's concerns," said Troxler. "It is important that we continue these conversations so the FDA can hear concerns from real farmers across the country. Postponing these rules will allow needed time for FDA and the states to make progress on a state-federal partnership on food safety. This partnership must be in place before implementation begins."

Vermont Secretary of Agriculture Chuck Ross will make food safety a priority for the association during his tenure as the President of NASDA in the upcoming year.



National Association of State Departments of Agriculture
 4350 North Fairfax Drive
 #910
 Arlington, VA 22203
 Tel: 202-296-9680
www.nasda.org

“NASDA is fully committed to food safety and the successful implementation of FSMA,” said Ross. “We must take the time to get this right for the sake of our producers, processors and consumers. I look forward to working with our partners and consumer groups to engage Congress and FDA in developing an implementable food safety program.”

NASDA is a nonpartisan, nonprofit association which represents the elected and appointed commissioners, secretaries, and directors of the departments of agriculture in all fifty states and four U.S. territories. To learn more about NASDA, please visit www.nasda.org.

-30-



National Association of State Departments of Agriculture
4350 North Fairfax Drive
#910
Arlington, VA 22203
Tel: 202-296-9680
www.nasda.org

NASDA Draft Water Comments

Compliance with water quality standards promulgated in the proposed rule will be the single greatest obstacle for fruit and vegetable producers regulated under the rule. Many farms that use surface water indicate that the water quality requirements & testing intervals proposed in the rule will put farms out of business.

It is NASDA's position that FDA should not finalize water quality standards proposed in Subpart E until a later date. For several reasons, it is appropriate for the FDA to take additional time to set relevant water quality standards for agricultural water: the current recreational water quality standards being used are unrelated to the use of agricultural water used during growing activities for covered produce; by FDA's own admission, these numbers were selected as a close approximation; it would be most effective for FDA to conduct research related to agricultural water before setting a standard, rather than after as is currently proposed; FDA is under a deadline to promulgate produce safety standards, but is NOT under a deadline specifically related to water quality (indicated by the delayed implementation of water standards); water quality standards will also apply to produce offered for import, if the science fails to establish these standards directly related to food safety, they may be successfully challenged under World Trade Agreements.

As a result, it is NASDA's position that food safety requires the FDA to reserve the current Subpart E for additional time necessary while research can be coordinated between FDA and appropriate stakeholders to set appropriate water quality standards. After research into agricultural water and setting relevant water standards, FDA should delay implementation of the water quality standards incrementally. This will allow farmers, labs, and states to prepare for effective implementation of water quality standards.

In the preamble, the FDA indicated its use of the EPA recreational water quality standards for agricultural water used during the growing activities for covered produce (other than sprouts), which are only written as guidance to the states for recreational water quality. Primary contact recreation typically includes activities where immersion and ingestion are likely and there is a high degree of bodily contact with the water, such as swimming, bathing, surfing, water skiing, tubing, skin diving, water play by children, or similar water-contact activities. These standards have not been set in final regulations by the EPA, the agency that researched & established the standard. This is altogether different than the way agricultural water is used by farmers. This makes the recreational water quality standards proposed by FDA an inappropriate measure for food safety.

Agricultural water is used in covered activities on covered produce throughout the growing season for activities such as irrigation and preparing crop sprays as well as washing and cooling harvested produce. As such, the water quality standards of a swimmer ingesting water are irrelevant to food safety and agricultural water used during growing activities for covered produce.

Rather than set standards which are already known to be inaccurate, FDA should fund research into determining appropriate model organisms as indicators of pathogen contamination (over a range of fresh raw agricultural commodities), the determination of an appropriate log reduction based on the interval between contact and consumption, and the effectiveness of other agricultural water quality standards such as the World Health Organization's.

FDA has already acknowledged that the water quality standards require significant research and FDA has seen that in many cases, a variance from the water quality standard is the only way that farms will be able to remain in production (for example, consider the dry onion growers in Oregon & the farmers using water from the Rio Grande for irrigation). FDA has set an extraordinarily high bar to states seeking variances, one that the FDA has not complied with in setting the proposed water quality standards (FDA relied on recreational water standards unverified by food safety protection). Under Subsection 112.173(c), the FDA requires a state (or nation) seeking a variance to establish that the different procedure is "reasonably likely to ensure that the produce is not adulterated" and will "provide the same level of public health protection" as under this part. NASDA is concerned that the second standard, requiring the "same level of public health protection" will likely require the use of risk modeling through the use of a yet undisclosed risk matrix. It is imperative that FDA provide additional information as to the second standard and the risk indexes that will be applied to numeric standards and intervals proposed under this part (as to both the water quality standards and the biological soil amendment application intervals).

The requirement to "discontinue use" if a test result falls outside the numeric E. coli standards is severe and may result in the loss of food product if alternative water is not available. Moreover, since there has been little information shared about what constitutes the "EPA approved treatment of water," NASDA believes that few options will be available to organic farmers and may result in additional loss of product. Moreover, because of the perishable nature of produce and the interval between sampling and the test result, it is possible that produce will have already left the possession of the farmer by the time the result is available. NASDA recommends FDA revisit the discontinue use standard and require remedial actions as an alternative.

Although FDA is under a Congressional mandate to set produce safety standards, FDA recognizes the importance of a longer implementation period for the water quality standards, evidenced by the two-year delay in implementation of water quality requirements. It is on these grounds that NASDA recommends FDA reserve Subpart E for the additional time necessary to perform relevant research into water standards for agricultural water and food safety based on indirect contact with the consumer rather than the EPA primary contact recreational standard.

Below is a list of the varying concerns of NASDA members related to water quality:

Questions about verification practices for other standards.

Clarify the requirements related to sampling location. FDA should better define sampling methodology for agricultural water including locations within the source that samples should be pulled from. The location of the sample will impact the result. Should samples be pulled from the source and the outlet (sprinklers)?

A definition is needed for how far up into a watershed a farmer is responsible for testing for contamination. Does the responsibility stop at the farmer's property line, or does it extend to properties beyond the farmer's control? NASDA seeks clarification as to how far up the watershed producers are responsible for monitoring the watershed for potential sources of contamination. It would seem unreasonable to expect identification of sources of contamination. Can producers reasonably be expected to identify potential sources of contamination significantly further up the watershed?

Proposed water quality standards create a benchmark of water quality that many farms will be unable to meet. NASDA proposes that FDA reconsider its water quality standards taking into consideration regions of the country where it is already known that surface waters do not meet water quality standards and other water sources are not available.

Provide an example of what FDA envisions as protected surface water. Inspection and maintenance of irrigation systems "under the control" of the producer is likely attainable; however, surface water users are completely dependent on the irrigation system outside the control of the producer. What waters are defined as under the producer's control? Many producers have very little control over surface water arriving to their farms.

Clarify treatment methods that are allowed to be used to bring water into compliance prior to the rule being implemented and recognize that the allowed methods may conflict with mandates from other state and federal agencies related to pesticide safety and water quality. Are adequate EPA approved irrigation water treatment methods available? How many antimicrobial pesticides are registered or labeled for use? Irrigation water chlorination systems are available, however, what will be the environmental impact of using this treatment method? These will give producers a more clear understanding of the costs and time involved in ensuring their water can be in compliance. It appears that providing treatment of irrigation water as an alternative may not a viable option given there are no EPA approved products, even with the delayed implementation period. If irrigation water used on organic crops does not meet the acceptable level and is then treated, the product ceases to be organic.

Please explain the rationale for selecting the 7-day sampling frequency. Is the science based on different field and climate conditions or just in labs? If pathogens can get into the water at any time, why the frequency of 7 days (and not 6 or 14)?

NASDA recommends using the GAP standard that establishes a testing schedule based upon the type of water source – well, spring or surface water. This simplifying of the testing will boost producer compliance. Testing surface water used for irrigation every seven days is onerous from both time and cost perspectives from many producers. NASDA suggests a more targeted approach based upon the level of E. coli historically found in the specific water source; whether the water is being used for overhead or drip irrigation, with overhead use requiring more frequent testing; and adjustment to the testing schedule based upon a baseline reading being taken at the start of the season.

Specify the circumstances in which water testing is required and at what frequency it is required. Is the 7-day frequency specific to farms that use irrigation on a regular basis? Should these frequencies be modified for farms that only use irrigation on intermittent occasions? For example, should a farm that uses irrigation one day a month be testing at the same frequency as a farm that uses irrigation daily? The proposed rule seems to indicate that producer must test water “at the beginning of each growing season, and every three months thereafter”. However, the table under 112.45 (b) seems to indicate if the water is from a river or lake, testing must be done every 7 days – or is that only if they suspect there is significant run-off? The seven day sampling requirement may be unattainable for producers using surface water; they may only request, receive, and irrigate every three weeks (taking into account the differences in water availability in American (riparian), Western and California water laws).

Testing at the beginning of the season is realistic for determining critical issues followed by testing closer to harvest, which would be more critical than throughout the growing season. Testing irrigation water (if irrigating using surface water) every 7 days will be challenging for many producers in terms of both time and costs. NASDA hopes that FDA considers the following in regards to testing frequency:

Find a way to recognize that not all surface waters are equal - some might be more likely to have E. coli and some might be less. If the farmer is using the surface water for overhead irrigation of crops that are eaten raw, then they have to test frequently; if they are drip irrigating, the testing could be less frequent (especially if under plastic). Take a baseline reading at the beginning of the season and then adjust the frequency of testing based on that baseline.

Define what FDA considers the beginning of the “growing season”. This term is used in several places in the Produce Safety Rule. What is generally known as the growing season contains a period of time where the edible portion of the produce is not yet present. Therefore, the requirement to start Agricultural water testing at the beginning of the growing season will cause confusion. NASDA suggests that Agricultural Water testing not be required until the edible portion of the produce is present.

Please clarify the expectation for water used for freeze protection in spring prior to the “growing season”.

NASDA suggests that a geometric mean only be used when water is tested at a high frequency. When lower frequency testing is performed, it will be very difficult to maintain the geometric mean stated in the rules, as one test could throw off the mean. For example, if irrigation is only done three months a year and monthly testing is performed, only three tests a year will be completed. If the first test result is 131 MPN and the second test is 200 MPN, the geometric mean is now above the limit even though the individual sample limit was not exceeded. Should a farm follow the mitigation step in this situation? The only way to get the mean down back below 131 would be to have a very low count.

The final rule should be written to allow flexibility within the agricultural water section to allow a risk-based modeling approach when an appropriate model has been designed. Several states have replaced water-testing programs with a risk based modeling approach to address recreational water safety. Instead of using test results to determine if recreational water is safe, modeling programs that calculate the

risks of a given source are designed to accurately predict when water will be outside acceptable ranges. Has FDA considered this approach to Ag water safety? The final rule for agricultural water should allow flexibility for determination of risks, indicator tests and testing methods that can be used by industry. There should be a means for industry to use new technologies that have not yet been approved by FDA to test for E. coli. Also, there should be flexibility to allow alternative indicators for water safety.

What lab qualifications are required for Agricultural Water testing?

Please clarify how the Irrigation water standards apply to ground crops like onions, carrots, etc. vs. tomatoes, cantaloupe, cucumbers vs. cherries, apples, peaches that never hit the ground.

Please clarify the expectations regarding hoses that are used to convey the required potable water used for washing and harvesting activities for covered produce. Are food grade hoses required for these activities? If potable water is run through a non-food grade garden hose, is it still considered potable?

Please clarify how the Irrigation water standards apply to ground crops like onions, carrots, etc. vs. tomatoes, cantaloupe, cucumbers vs. cherries, apples, peaches that never hit the ground.

Greater consideration should be given to standards more equivalent to the World Health Organization (WHO) standard (water quality of 1,000 CFU/100 ml. for root crops and 10,000 CFU/100 ml. for leaf crops). Failure to more closely align with the WHO may reduce U.S. economic competitiveness in world markets.

Clarify how the water testing requirements apply to water used to remove “field heat” from produce. Testing water for taking out “field heat” (during harvest) or post-harvest: Continually monitoring post-harvest water that product are immersed in will require infrastructure/equipment costs of digital monitors. Some farmers take out “field heat” using dunk tanks in the field; the product is then rinsed again in the pack house. It is not clear whether a farmer would have to continually monitor the water quality in a dunk tank used for removing “field heat” (especially if farmer is then triple-rinsing/using sanitizer in the pack house).

Under 112.50 (b) (5), the regulation should require that the actual laboratory report should be kept on file, and not simply “a record” of water test results.

Proposed Sec. 112.42 requires inspection of the entire agricultural water system at the beginning of each growing season. Does a record of this inspection need to be kept by the grower?

Suggest that farms that test their agricultural water infrequently should test it at the time of highest probability of contamination (generally in the Spring for both surface waters and groundwater subject to surface water influence).

Proposed Sec 112.42 requires immediate discontinuance of water that has been determined to be unsafe. Should there also be a requirement to not harvest/sell any produce that may have been contaminated by that unsafe water?

Proposed Sec 112.44 (b) requires that if water is found to be contaminated with E. coli, that system must be re-inspected and re-tested, OR the water must be treated. Suggest that in cases where the water is treated, that it be required to also be RE-TESTED (and perhaps re-tested throughout the water system) to ensure that treatment was effective. This is in line with EPA Public Water System testing requirements.

On page 221 paragraph 3 of the Rule Summary, it states that the W.H.O. minimum microbial quality for root crops eaten raw is 1000 CFU/100mL generic E. coli and 10,000 CFU generic E. coli for leaf crops. Assuming that "leaf crops" means "leafy greens", shouldn't these two standards be reversed?

Suggest further clarification of the definition of "Agricultural Water". The current proposed definition includes water "intended to, or likely to, contact covered produce or food-contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods...)" Does it include water that contacts ANY PART of covered produce, or only the edible portion?

Is water used for INDIRECT water application methods not subject to water quality standards of any type? Some water sources, such as those subject to contamination by livestock, may present a risk of contamination even if indirectly applied close to harvest.

Regulations should note that in some states, application of pesticides to any surface waters of the state (including irrigation waters) is subject to permit requirements.

Under 112.44, only water applied to crops by "direct water applications methods" is subject to water quality standards. Since the definition of "Direct water application" includes only water directly applied to the harvestable portions of the plant, I am concerned about the application of these guidelines in some circumstances. For

example, sprinkler irrigation of carrots would be considered “indirect application” of water, and there would be no requirements for water quality. Would a grower then be allowed to apply contaminated surface water via sprinkler or drip irrigation to these carrot rows right up to harvest? If this is the case, it would present unforeseen risks. And while produce contaminated in this way would be considered adulterated under Section 402(a)(4) of the FD&C Act, it seems more prudent to provide safeguards against this type of possible contamination. Establishment of pre-harvest intervals for the application of non-treated water for certain crops or circumstances would prevent this.

Suggest adding requirements that any water source (surface or groundwater) be re-tested as soon as possible after any event that could adversely affect water quality.

Maria Knirk
616.914.8408