

Collaborative Food Safety Forum (CFSF)

Agricultural Water Standards and Testing Requirements in the Proposed Produce Safety Rule: *Draft Workshop Summary*

August 8, 2013
Washington, D.C.

Background

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the [Collaborative Food Safety Forum](#) (CFSF or Forum). Invited representatives from federal and state agencies, industry, consumer advocacy groups, and academia attended a workshop on August 8, 2013 to discuss the agricultural water standards in the Proposed Produce Safety Rule as a part of the Food Safety Modernization Act (FSMA) implementation.

The goals of the workshop were to:

- Present and discuss the proposed agricultural water standards in the Produce Safety Rule, as well as other agricultural water standards, and the accompanying scientific bases and other rationale used in their development;
- Discuss the science behind and uses of agricultural water and associated risks;
- Discuss select targeted questions posed in FDA's proposed Produce Safety Rule on agricultural water quality, focusing on section IX (Comments); and
- Discuss approaches to determining the adequacy of scientific data on and/or documentation for alternative agricultural water quality standards that must demonstrate that the alternative approach provides the same level of public health protection as the proposed standard

The outcome of the workshop was:

- A document highlighting ideas and principles identified in the Collaborative Food Safety Forum for setting an agricultural water standard, appropriate testing protocols, and pathways for meeting the standard as part of deliberations regarding the proposed produce safety rule (*this document*).

This workshop opened with a welcome and remarks from Sandra Eskin from Pew, Angela McGowan from RWJF, and Mike Taylor, Deputy Commissioner of Foods and Veterinary Medicine at the Food and Drug Administration (FDA). Abby Dilley from RESOLVE followed with a review of the workshop's goals, outcomes, and agenda.

Overview and Discussion of Proposed Produce Safety Rule Approach to Setting an Agricultural Water Standard

Samir Assar, Director, Produce Safety Staff, FDA, presented an overview of the key principles shaping the proposed rule, including:

- The rule considers risk posed by practices, commodities, and conditions;
- It is science- and risk-based;
- It takes into account a broad range of agricultural practices;
- It excludes low risk commodities; and
- It is flexible and allows for variances or alternatives.

Dr. Assar stated that FDA has drafted a Qualitative Assessment of Risk document as part of the rule that is also available for public comment. The risk-based approach taken by FDA means that the most stringent requirements would be imposed for agricultural practices that pose the greatest risk. The proposed rule focuses on five identified possible routes of microbial contamination of produce, including:

- Agricultural water;
- Biological soil amendments of animal origin;
- Worker health and hygiene;
- Equipment, tools, buildings and sanitation; and
- Domesticated and wild animals.

For regulatory purposes, *agricultural water* is defined as “water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces.” The proposed rule also states that agricultural water “must be safe and of adequate sanitary quality for its intended use.”

Generic *E. coli* is used as an indicator organism; its presence above a determined level indicates that the water quality may pose a risk to human health. The proposed rule uses as the limit on *E. coli* contamination the EPA recreational standard for water, 235 CFU per 100 ml and 126 CFU per 100 ml geometric mean.¹ This standard is epidemiologically based, familiar to most industry groups, and applies to water that contacts the harvestable portion of the product.

Frequency of testing requirements in the proposed rule varies depending on the water source:

- For untreated surface water with potential for runoff, the testing interval is seven days;
- For protected, controlled surface water with no potential for runoff, the standard is once every three months after the growing season begins; and

¹ Note that the EPA has changed its recreational standard for water to 410 cfu per 100 ml, but because of timing, this was not reflected in FDA’s Proposed Rule

- When any test show a generic *E. coli* level that exceeds the standard, water must again be tested and found to be within the acceptable range before it can be used.

After Dr. Assar’s overview of the proposed rule, several questions were raised and discussed. A question was asked about how the emphasis can be placed on the risk posed by water, yet the timeline for compliance is quite long. FDA staff pointed out that rule making and effective implementation requires balancing between establishing a regulatory framework, a period of preparation to meet requirements, and then the implementation and enforcement of those requirements. Further, it takes time to develop a framework that is based on science, covers such a complex set of variables, is flexible enough to accommodate those variables, and yet, establishes enforceable standards. The Agency understands some of the limitations of the standard as proposed and is focused on being as flexible as possible throughout the process of determining a final rule, while also making strides in improving the safety of the food supply. FDA stressed that the testing requirement is about knowing and characterizing one’s water source, not checking a box to know water is safe for one week. The requirement is intended to reflect a concept and overall approach that incentivizes the safe use of water, and prompt corrective action, based on testing, to ensure water used is safe.

Dr. Assar’s slides can be found [here](#).

Microbial Contamination Risks from Agricultural Water Use

Trevor Suslow, Extension Research Specialist, Center for Produce Safety, University of California Davis, presented ideas on key topics he thought would catalyze dialogue regarding microbial contamination risks from agricultural water use. Dr. Suslow suggested that current indicators of agricultural water safety do not reliably reflect recent or episodic fecal contamination. The development of a more comprehensive approach is needed to accurately determine risk—one that considers source, region, environmental influences, system integrity, and water temperature at the point of extraction. He also pointed out that most producers growing produce covered in the proposed Produce Safety Rule do not have the expertise to adequately assess the risk profile of their water sources. Further, those farms that do not have a food safety expert on staff will only be able to achieve compliance, which is not necessarily the same as a higher level of safety or reduced risk.

Dr. Suslow also suggested that an approach including farm irrigation “permit to operate,” wherein each farm would conduct an expert risk assessment and inspection specific to its region, crop, and practice.

Following the presentation, there was discussion about different tests that could identify chemical or biological agents in the water, as well as other human or animal waste that can contaminate the edible portions of crops covered in the proposed rule. Better testing and tools are needed across the board to address many of these potential contaminants, including indicator species. The lack of more effective methods was noted as a significant concern of the produce industry representatives.

Dr. Suslow's slides can be found [here](#).

Basis for the Proposed Standards

Samir Assar and Erick Snellman, Senior Policy Analyst, FDA, explained the basis for the proposed standards. Key considerations, such as the need for water to be safe and of adequate sanitary quality for its intended use, and the importance of examining water sources to determine their potential risk of contamination, were taken into account. He also presented a table illustrating the relative likelihood of produce becoming contaminated based on water source, and the importance of producers being able to assess their production systems and any risks.

Dr. Snellman also provided an overview of the rationale for using EPA's recreational water standard (235 CFU per 100 ml and 126 CFU per 100 ml geometric mean), including the fact that this standard is known by the industry and other stakeholders, is appropriate for direct application methods (i.e. contact with harvestable portion of the crop), and that FDA allows for documented alternatives. He also discussed the overall approach to proposing the frequency of testing – again, the fact that it depends on the water source.

During the discussion after the presentation, participants expressed concerns about the use of generic *E. coli* as the indicator organism because, among other reasons it may not be associated with pathogenic contamination. FDA reaffirmed that *E. coli*, while not being an ideal indicator, is one with a scientific basis, is relatively inexpensive to test for, has a variety of testing formats, and is a somewhat familiar standard. Other indicator organisms were mentioned and discussed, including *Bacteriodes*, but challenges exist with each, including lack of scientific basis and the limited availability and high cost of associated tests. Given these various considerations, FDA believes generic *E. coli* is the most logical choice. As one participant suggested, "It is the best worst indicator organism."

There were additional questions around alternatives and variances, frequency of testing, and use of the EPA standard. There was much discussion around who – or what sort of entity – could apply for a variance and/or an alternative – and what that pathway for each looks like. FDA indicated that it will develop and update guidance and other documents as alternatives and variances are approved to share information about acceptable approaches. FDA staff also requested input on what growers and others think could be acceptable, science-based alternatives and encouraged participants to offer suggestions, both as part of their formal written comments to the docket and informally as well.

The frequency of testing has been a source of much confusion based on comments to date, as well as the meeting deliberations, and FDA is looking for ideas and suggestions to help clarify the language. The intent of this part of the rule was to allow growers to characterize their water as part of a risk assessment plan. Agency staff asked participants to think about this in terms of

an overall approach and concept, regardless of what the actual numbers (both the standard and frequency of testing) proposed or established in a final rule.

Their slides can be found [here](#).

Variability in the Use of Water for Produce Production and Associated Risk Assessment and Management

As context for discussion about the proposed requirements in the rule, several participants presented on existing water standards and testing protocols; factors or considerations for why the currently proposed strategy does not work or needs to be tailored for a specific commodity; and other ideas FDA should consider, included in the summary below, as well as the attached slides from the presentations.

Leafy Greens Marketing Agreement

Dave Gombas, Senior Vice President, Food Safety and Technology, United Fresh Produce Association, presented background on the California Leafy Greens Handlers Marketing Agreement (CA LGMA), specifically, its provisions on agricultural water. The CA LGMA was developed in response to several *E. coli* outbreaks associated with leafy greens, in particular the one that occurred in 2006. It is a voluntary framework for best practices intended to reduce risk of bacterial contamination from agricultural water. Development of that standard also took into consideration water sources and use; it also used generic *E. coli* as the indicator species, believing it to be the best surrogate for fecal contamination available at the time.

The CA LGMA does not make any determination of “safe” or “unsafe” levels of the water or contact surfaces of the crop but, rather, indicates best practices or actions for preventing unchecked increasing bacteriological densities. Best practices, outlined in Dr. Gombas’s presentation, include a similar risk assessment approach to agricultural water, taking in to consideration the source of the water and any factors that may increase or reduce the risk of that water being the vector for bacterial contamination. Factors include when (pre-irrigation, during or post harvest, packing, storing, etc.) and where in the water system (i.e., proximity to the point of contact with the crop) testing should occur, as well as recordkeeping protocols and other variables associated with agricultural water use. Other key aspects of the CA LGMA are proposed remedial actions to be taken based on assessments of risk, including water testing, as well as proposed protocols for crop testing should water be used that exceeds acceptable levels for *E. coli* O157:H7 and *Salmonella*.

Dr. Gombas also walked through variations in the approach based on location – specifically, the differences with the approach to water proposed for leafy greens in Arizona versus California – and why.

During the discussion following Dr. Gombas's presentation, it was noted that the CA LGMA was reviewed and considered closely in the development of the proposed Produce Safety Rule in general and the water quality standards in particular. Some participants suggested the CA LGMA was not a good model to use for a variety of reasons, in particular, that it was developed in the context of crisis management. Other participants indicated the CA LGMA was the most comprehensive set of standards to date and was a good model as it has an overall, comprehensive framework; is familiar to the industry; and is based on current science. However, it also was pointed out that the CA LGMA standards are not based on safety, but on key criteria indicating contamination and associated action levels to reduce further contamination or unchecked bacterial density levels.

In regard to FDA's proposed Produce Safety Rule, many participants voiced concern over having one agricultural water standard for all commodities that fall within the established parameters (i.e., have edible contact surfaces or can become contaminated in their handling or consumption). These participants also stated that given the wide variability in risk potential of each commodity, low risk commodities might warrant an exception, alternative approach, or variance from that standard. Further, there was discussion over how a standard might evolve over time, and in conjunction with this, what would happen as the science improved. One participant suggested FDA could put in place some mechanism in the final rule to allow for changing the standard and, in a more timely process than a whole, new rule making effort. Some suggested putting the numerical standard in a guidance document, which could be updated routinely. However, recommendations contained in guidance are not enforceable, and some participants were not supportive of having no established, enforceable standard, and further questioned whether this approach could meet the intent of FSMA and what FDA is mandated to do.

Dr. Gombas's slides can be found [here](#).

Other Standards and Testing Programs

Will Daniels, Senior Vice President for Operations and Organic Integrity at Earthbound Farms, presented on water quality standards and testing programs specific to Earthbound. Its program tests for both generic *E. coli* and specified pathogens and uses a risk assessment/risk management approach. PCR testing is used and samples are analyzed by a third-party lab located on the Earthbound Farms campus. Results of testing, based on specified criteria, trigger action steps to prevent use of unacceptable water and to identify and address the source of any problems detected. Mr. Daniels shared observations based on his company's experience—namely that generic *E. coli* is not a good indicator for pathogens, activities like dredging can lead to elevated counts of generic numbers, and that there have been few linkages between contaminated water, a contaminated crop or soil, and human illness. There was also additional

discussion about testing the *source* of water rather than the *end use*. Mr. Daniels stated that the majority of Earthbound's non-compliant results are due to the distribution system rather than the water source. The proposed rule, however, requires testing at the source and not after the distribution system. Further, he suggested a metric should be fluid, not fixed, and be adjustable so it can be further informed by scientific advances.

Mr. Daniels' slides can be found [here](#).

Mike Aerts, Director of the Marketing and Membership Division of the Florida Fruit and Vegetable Association, presented on "the tomato rule" and how Florida's Legislature granted the State Department of Agriculture the ability to regulate practices promoting tomato safety beginning in 2008. This collaborative effort between industry, academia, and state officials, called for all agricultural water to meet recreational water standard. Groundwater used in agriculture is monitored annually and surface water, quarterly. Auditing is done on a routine and random basis and enforcement measures are included. Mr. Aerts described the process as largely productive and successful.

Other Variability in the Use of Agricultural Water and Any Associated Risk Assessment and Management

Mark Seetin, Director, Regulatory Policy and Industry Affairs, U.S. Apple Association shared insights about growing and harvesting practices and agricultural water use in the U.S. apple industry. He suggested that surface water testing requirements as proposed are too expensive and extensive for a crop with a seven month growing season and a safe track record. As far as he knew, and in the articles he highlighted, apples have not been the identified source of any foodborne illness outbreak. Mr. Seetin concluded that the standard as proposed would pose substantial issues of liability, undue expense, and the potential for negative impacts on production practices for growing the fruit, including use of water to prevent sunburn. He also stated that aggressive remediation practices, including the use of harsh chemicals, could potentially harm the soil.

During discussion following the series of presentations, participants noted that some states have their own guidelines for water quality risk assessment, testing, and risk management, and wondered how these efforts would be affected by the Produce Safety Rule – and either could serve as a variance or would be superseded by it. An example included Washington State's guidelines for well water testing, which is frequently used for ranching. The *drinking water* standard states that the owner of a well must test it at least once per year for coliform bacteria and nitrates, and although no agency directly regulates the use of this water for agricultural purposes, well water must generally comply with the drinking water standard. Participants also discussed the great variability among regional growing seasons, some with episodic growing seasons, while others have year- round seasons. In these cases, some participants felt that the

proposed testing frequency could be too labor and resource intensive and lacked relevance depending on the type of water source and/or commodity.

It was also noted that certain commodities, such as apples, have not experienced any sort of outbreak event. A variety of perspectives were raised about this history, ranging from proposing this as reason for not regulating some commodities in the same way, to not assuming that because outbreaks have not yet occurred, that this is evidence that some commodities are inherently safer – at least without more research to verify. In thinking about reasons why certain commodities have not experienced outbreak events, several participants pointed out that research about outbreaks is almost always driven by an outbreak event and, therefore, not every commodity has been extensively researched. This retrospective approach to research limits the understanding of factors determining why some commodities have experienced problems while others, to date, have not. Thus, further research is critical for improved understanding of the role agricultural water quality plays in food safety.

Mr. Seetin's slides can be found [here](#).

Opportunities for Flexibility in Meeting a Standard

Linda Harris, Senior Policy Advisor, FDA, presented a paper developed by a team of scientists that outlined a framework for studies necessary to determine whether a variance is based on adequate research. . Background on the process for developing the framework, as well as what the framework proposes and why, was discussed. Ultimately, Dr. Harris stated, the committee of researchers working to develop the framework struggled with how to determine under what conditions or body of evidence, a variance is valid, particularly in regard to determining when an alternative approach meets an equivalent level of public health protection. The framework, while providing a comprehensive approach, is difficult to translate into a regulatory standard.

Participants had questions regarding the applicability of this framework to their daily work or how it could be applied to their specific commodity or farm growing a variety of commodities. Their concern was that this framework was a more useful tool for researchers rather than growers/producers. It was pointed out that FDA intended this research to be a way to illustrate what kind of data, and methodologies for collecting data, are needed, rather than a “how to” guide for each grower whose commodities or operations are included within the scope of the proposed Produce Safety Rule.

One approach discussed was for producers, potentially in a collaborative effort, to reach out to a cooperative extension or university for research and data collection assistance, as well as the design of an overall approach. Growers were not necessarily expected to have the means to do this kind of extensive methodological or design work required to carry out a study proving an

equivalent level of public health protection. The ultimate vision for these types of studies is that they become models for achieving a variance by showing how this information could be modified in other regions, for other growers, and for other commodities.

Dave Gombas presented on using a different approach to quantitative risk assessment (QRA) as cited in the proposed Produce Safety Rule, and discussed by Linda Harris. The QRA described by Dr. Gombas was developed using expert opinion and data taken from published studies and proposes a protocol that can be used to demonstrate “low risk.” Drawing on existing data regarding disability-adjusted life years (DALYs), this approach to a QRA estimates the potential linkage between the concentration of pathogens and the risk to the public’s health in a variety of scenarios. It also takes the specific commodity into consideration in the calculation. It was suggested this approach provides a possible means of establishing a quantitative measure of “public health equivalence.”

Dr. Gombas’s slides can be found [here](#).

In considering how this approach to QRA could affect farms that grow a diversity of products, it was suggested that the crop of highest risk be used to drive the analysis for the whole operation. Many participants, however, expressed concern that this methodology would be too burdensome and difficult for farmers to conduct and integrate into their operations. Some participants also suggested this approach placed too much emphasis on a “precautionary principles” strategy rather than being a more pragmatic, preventive approach.

Other participants supported the general QRA approach because it can be used to determine a variance or alternative means of assessing and managing risk. Associations, state agricultural departments, and extension services (if properly funded) could be tapped to conduct the work and establish alternative approaches, which could then, in turn, be adopted and referenced by growers. One suggestion included an outbreak-by-commodity approach wherein only commodities that have experienced significant outbreaks in the past would be subject to the requirements of the rule. Other participants were concerned with this reactive-, rather than preventive-, focused approach.

FDA noted that the timeline for implementing the current rule is longer-term. If the final rule were released by June 2015, compliance would not be required until four years later. Between now and summer of 2015, FDA will be reviewing all comments submitted to evaluate alternative standards and variances.

Discussion of Principles for an Agricultural Water Quality Standard Rule

Many participants disagreed with or were hesitant about integrating a numerical standard into the proposed rule, while others thought it was necessary for giving concrete dimensions to an overall protective approach to food safety for a key route of contamination of produce, agricultural water, and is essential for compliance and enforcement. Some participants suggested the scientific basis supporting a numerical standard was lacking, and one participant noted that it was a presumption to identify and build requirements around agricultural water as definitively responsible for outbreaks. Further, it was suggested that more time and research was needed before justifying a numerical water quality standard. The CA LGMA was pointed to as an example of a numerical standard that had little evidence to support public health improvement, but has been used to scale best practices considered to improve food safety. Some participants stated there is a scientific body of evidence that supports a numerical standard. FDA staff has indicated they are willing and open to integrating a mechanism and/or approach to updating the standard as scientific research advances knowledge, and FDA reiterated encouragement for the development of concrete, documented alternatives as a means of achieving the public health benefit using flexible strategies.

One participant noted the overall focus for agricultural water quality needs to be on putting the right practices into place, not just achieving a single standard for growers. The reality is the public, and therefore retail outlets, demand a safe food supply, which is determined by more than just the establishment of a standard. There was general agreement and support for more research to advance science and promote the most effective and appropriate production practices.

Lastly, many of the participants encouraged continued deliberations on these issues, including feedback on the overall approach of the proposed Produce Safety Rule, ideas for more effectively implementing the intent and overarching philosophy into a logical and practical approach, and building in flexibility for adapting to different commodities with verifiable approaches, as well as updating standards or practices as scientific research provides new insights and information.

Key questions for further deliberations include:

- Is the overall approach to establishing water standards appropriate or philosophically on track? (In other words, are the key principles shaping the proposed rule on target? Key principles highlighted by Dr. Assar were the following:
 - The rule considers risk posed by practices, commodities, and conditions;
 - It is science- and risk-based;
 - It takes into account a broad range of agricultural practices;
 - It excludes low risk commodities; and

- It is flexible and allows for variances or alternatives.)
- What is the correct numerical standard, given it might differ from commodity to commodity?
- How can FDA look at a system of targeted testing and characterization of water that would be less intrusive than what has been proposed?

Participants proposed other areas for additional dialogue, including whether and what corrective actions are suggested or required when water quality standards are exceeded, and greater clarity around the process by which alternative methods or strategies may be implemented.