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FOOD AND DRUG LAW JOURNAL

VOLUME 72 NUMBER 3 2017

FDLI GEORGETOWN LAW O'NEILL INSTITUTE FOR NATIONAL & GLOBAL HEALTH LAW GEORGETOWN LAW

Assessing the Scientific Basis of the Agricultural Water Provision of the FSMA Produce Safety Rule

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ABSTRACT

The Food Safety Modernization Act of 2011 (FSMA) requires the U.S. Food and Drug Administration (FDA) to establish science-based minimum standards for the safe production and harvesting of raw produce. This paper examines the scientific basis of the Produce Safety Rule's agricultural water provision, highlighting several criteria: microbial indicators for fecal contamination and decay rates; water source testing; wash water temperature; and water treatment. Analysis finds that FDA made a good faith effort in rulemaking. Implementing the rule, however, is complex for both producers and regulators, requiring additional research to fill gaps in the scientific literature and gaps in knowledge about application of the standards.

INTRODUCTION

FSMA,[1] a 2011 amendment to the Federal Food, Drug, and Cosmetic Act (FDCA), is intended to enable FDA to better protect public health.[2] It requires FDA to establish science-based minimum standards for the safe production and harvesting of raw fruits and vegetables, and to adopt a final regulation based on known safety risks. This final rule identifies the procedures, processes, and practices designed to meet at least two goals: 1) to prevent the introduction of known or foreseeable hazard into produce; and 2) to provide a reasonable assurance that produce is not adulterated in accordance with 21 U.S.C. § 342.

The purpose of this paper is to examine the scientific basis of the regulations that implement FSMA, particularly the agricultural water provision of the final rule on Produce Safety, known hereafter as the Final PSR. We focus on water as it is a provision of the Final PSR in which FDA used the largest number of scientific studies in rule development.[3] The agricultural water provision of the Final PSR is

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1 21 U. S. C. § 2201.

2 21 U.S.C. § 105 (C)(1)(A).

3 Standard for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74,353, 74,425 (Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 11, 16, and 112)

hereafter known as AWP. Also examined are the challenges to interpretation and implementation of these standards at the farm level, and the limitations for FDA in both rulemaking and in providing science-based guidance for compliance.

Previous studies examined the development and implementation of FSMA broadly;[4] whether FDA has the capacity to fully enforce subsequent regulations[5] and meet the regulatory training requirements; the economic impacts on small-scale production and international trade;[6,7,8] and the cost of implementation as it relates to operator size.[9] Accordingly, we will evaluate the AWP of the Final PSR to examine whether it is based on "sound science" and risk assessment, the foundation of FSMA. This is typically understood to be work that originates from "organized investigations and observations conducted by qualified personnel using documented methods and leading to verifiable results and conclusions."[10] Drawing on this understanding, FDA defines "sound science" as an approach that is based on scientific information, data, and results that are published in peer-reviewed journals, textbooks, or other proprietary research.[11] The justification for using proprietary research is in the Current Good Manufacturing Practices requirements for dietary ingredients and dietary supplements.[12]

FDA's risk assessment includes four components:[13]

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[4] Michaela Wattenberg-Tarr Oldfield, Public and Private Regulation - The Food Safety Modernization Act and the Governance of Food Safety in the United States (2015) (unpublished Ph.D. dissertation, Michigan State University) (ProQuest Dissertations Publishing, 3719825); Christa A. Drew & Fergus M. Clydesdale, *New Food Safety Law: Effectiveness on the Ground*, 55 CRITICAL REV. FOOD SCI. NUTRITION, 689 (2015).

[5] Debra M. Strauss, *An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business*, 66 FOOD & DRUG L.J. 353 (2011), http://papers.ssrn.com/abstract=1925008 (last visited Feb 21, 2016); Kristin Eads & Jennifer Zwagerman, *In Focus: Examining the New FDA Food Safety Modernization Act*, 33 HAMLINE J. PUB. L. POL'Y 123 (2011); Neal Fortin, *The United States FDA Food Safety Modernization Act: The Key New Requirements*, 6 EUR. FOOD & FEED L. REV. 260 (2011).

[6] Sara Roland, *Note, Food Safety Modernization Act's Produce Rules: Is the Increased Flexibility Actually a Burden on the Farmer?*, 20 DRAKE J. AGRIC. L. 437-452 (2015)., NATIONAL AGRICULTURAL LAW CENTER, http://nationalaglawcenter.org/publication/note-food-safety-modernization-acts-produce-rules-is-the-increased-flexibility-actually-a-burden-on-the-farmer-20-drake-j-agricultural-l-437-452-2015/ (last visited Dec 15, 2016).

[7] Sebastien Pouliot, *The Production of Safe Food According to Firm Size and Regulatory Exemption: Application to FSMA*, 30 AGRIBUSINESS 493 (2014).

[8] Neva Hassanein, *Matters of Scale and the Politics of the Food Safety Modernization Act*, 28 AGRIC. HUM. VALUES 577 (2011).

[9] Pouliot, *supra* note 7; Hassanein, *supra* note 8.

[10] *Sound Science*, SOC'Y OF ENVTL. TOXICOLOGY & CHEMISTRY (1999), https://c.ymcdn.com/sites/www.setac.org/resource/resmgr/publications_and_resources/setac_tip_soundsci.pdf (last visited Apr 25, 2016).

[11] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74,354 (Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 11, 16, 112).

[12] Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, 68 Fed. Reg. 12,157, 12,198 (proposed Mar. 13, 2003).

[13] Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce, FDA (2015), http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM470780.pdf (last visited Apr 23, 2016).

(1) Hazard Identification: a summary of the biological agents capable of causing adverse health effects that may be present in produce.

(2) Hazard Characterization: a qualitative description of the nature, severity and duration of the negative effects of microbiological hazards that may result from ingestion of contaminated produce.[14]

(3) Exposure Assessment:[15] an accounting of the likelihood of on-farm contamination from water, soil amendments, animals, workers, equipment and buildings, including estimates of the likelihood and frequency that contamination remains at the point of consumption.

(4) Risk Characterization: an integration of information from hazard identification, hazard characterization, and exposure assessment to qualitatively estimate the negative effects likely to occur in the population.

In the section that follows, a brief background on the rulemaking process contextualizes the regulatory landscape of the Final PSR. Next, is a summary of the AWP including the associated comments and scientific justification for the respective standard. We show that the AWP of the Final PSR is generally supported by the scientific literature. Yet, also acknowledged are weaknesses and gaps in the literature that support the provision, and the subsequent reservations that arise for both producers and regulators enacting the AWP of the Final PSR. We conclude by laying out three issues that have policy implications: 1) the gaps in water safety research; 2) the hidden compliance costs; and 3) the capacity to provide adequate guidance.

I. BACKGROUND OF FSMA RULE-MAKING

On January 16, 2013, FDA published its proposed rule titled Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR § 11, 16, and 112). At the same time, FDA published a draft of the Qualitative Assessment of Risk (QAR)[16] that informs the proposed science-based standards. The draft QAR received approximately 1,300 public comments on five topics outlined by FDA: the risk levels of certain commodities; the belief that larger farm size correlates to higher produce contamination risk; the need for incorporating risk management and assessment into the QAR; the lack of quantitative, science-based, risk assessment for microbial contamination; and the limitations of using CDC and FDA epidemiological records for assessing biological hazards in produce.[17]

Five experts in medical microbiology and pre-to-post harvest food safety from industry and academia conducted peer reviews of the draft QAR.[18] While the reviews

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[14] JOINT FAO/WHO CODEX ALIMENTARIUS COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, & WORLD HEALTH ORGANIZATION., CODEX ALIMENTARIUS: FOOD HYGIENE BASIC TEXTS ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene_2003e.pdf, (2003).

[15] *Microbiological Risk Assessment Series 7: Exposure Assessment of Microbiological Hazards in Food: Guidelines*, WHO & FOOD & AGRIC. ORG. (2008).

[16] *Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce,* FDA (2013).

[17] FDA, *Memorandum to the File - Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce – FDA Responses to Public and Peer Reviewer Comments*, (2015).

[18] *Id.*

were generally positive, one comment noted that gaps in the data limited the ability to understand the process of microbial contamination. Therefore, a degree of scientific inference in qualitative risk rankings was required. Reviewers also provided comments to improve the document including the selection of scientific references to support the QAR.

The final QAR was published on November 13, 2015,[19] noting five key findings:

(1) produce can be contaminated, and the vast majority of related illnesses are associated with biological hazards;

(2) the known routes of contamination from growing, harvesting, and on-farm postharvest activities are associated with seed, water, soil amendments, animals, worker health and hygiene, and buildings and equipment;

(3) all produce has the potential to become contaminated through one or more routes;

(4) commodity specific growing, harvesting, and on-farm postharvest conditions and practices may influence the potential routes and likelihood of contamination and possibly lead to illness; and

(5) postharvest handling practices such as washing, peeling, and cooking before consumption may impact the likelihood of contamination, and thus, may increase (i.e., cross-contaminate) or decrease (i.e., remove a possible contaminate) the possibility of consumer exposure.

The initial comment period for the proposed Produce Safety Rule was extended three times from the initial publication date in January to August in response to complaints that the original 30-days was insufficient. On September 29, 2014, FDA proposed new provisions and amendments, which were open for public comments until December 15, 2014.[20] This later set of comments are addressed in this paper as they immediately preceded the Final PSR that was published on November 27, 2015.[21] In total, approximately 15,000 comments[22] were made by consumers, legal firms, producers and cooperatives, trade and public health organizations, advocacy and consumer groups, and governmental organizations during the final comment period. These comments addressed four broad issues.

First, several comments were specific to the *science* supporting the proposed Produce Safety Rule including the use of a commodity-specific versus an integrated approach for developing the risk profiles and the inadequacy of empirical support (e.g., lack of comparative risk studies of different supply chain types). Second, the comments addressed *interpretation* of the proposed rule including the lack of guidance for both aquaponics and produce safety generally. Stakeholders also requested clarification of both the terminology and the equivalency of alternative methods of pathogen control including the associated analytical requirements.

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[19] JOINT FAO/WHO et al., *supra* note 14.

[20] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. 58,434 (proposed Sept. 29, 2014).

[21] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74,354 (November 27, 2015).

[22] Comments on the Final Produce Safety Rule were found by accessing the Final PSR, then clicking on "public comments." The number of comments on any particular topic is an estimate because FDA does not provide the number that were received on that issue. Comments were collected both by tracking the topics mentioned in the Final PSR and searching the comment database for particular word combinations.

A third set of comments were directed toward *implementation,* including how producers ought to reconcile the proposed PSR with existing industry guidelines and certification programs, handle non-biological hazards, and manage the seemingly excessive recordkeeping requirements. This group also included questions about the use of market incentives in lieu of regulation; the inclusion of prescriptive and/or inflexible quantitative metric requirements; the eligibility criteria for variances; as well as inquiries about why farm specific food safety plans were not required. A last set of comments focused on *equity* of the proposed PSR including concerns about FDA singling out on-farm produce contamination rather than the occurrence of contamination along the supply chain after produce leaves the farm; its fair application to both foreign and domestic farms; and the suspected burden for small-scale farms.

In addition, there were numerous concerned stakeholders of intersecting groups—those who have small-scale operations, those who are involved in short supply chains (e.g., direct and/or local sales), and those who use sustainable agricultural practices (e.g., organic, natural). Together, these stakeholders opposed the Final PSR.[23] Ultimately, their concerns were generally satisfied by the Tester-Hagan Amendment to FSMA (§ 112.5). Tester-Hagan exempted farms "that could demonstrate a previous three-year average gross income of less than $500,000 and over 50% of sales were to [consumers, restaurants, or retailers within a certain geographic region], or the average value of produce sold over the previous 3 years was less than $25,000."[24] Both food safety proponents and the agricultural industry criticized the amendment, stating that food safety issues could arise on farms of any size.[25] The compromise that led to the Tester-Hagan adoption was the addition of the "exemption withdrawal," which permits FDA to require small farms not meeting the minimum safety standards, or found to be linked to an outbreak, to comply with the Final PSR.[26] With the exemption withdrawal in place, all produce is potentially subject to the requirements of the Final PSR.

The Final PSR is specific to domestic and imported "covered produce," which is the harvestable part of edible crops.[27] "Covered produce" exemptions include those items that are rarely consumed raw and/or those that receive adequate commercial processing to reduce the presence of pathogens (e.g., *Salmonella, Listeria, E. coli*). For simplicity's sake, we drop the word "covered." Foreign farms that export to the

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[23] See comment from Carolina Farm Stewardship Association on the Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption 1 (Nov. 14, 2013) and comment from Slow Food (Oct. 31, 2013), docket FDA-2011-N-0921.

[24] Gregory M. Schieber, Note, *The Food Safety Modernization Act's Tester Amendment: Useful Safe Harbor for Small Farmers and Food Facilities or Weak Attempt at Scale-Appropriate Farm and Food Regulations?*, 18 DRAKE J. AGRIC. L. 239 (2013).

[25] Laurie J. Beyranevand, *Balancing Food Safety and Burdens on Small Farms*, 28 NAT. RESOURCES ENV'T. 17 (2013).

[26] See 21 U.S.C. § 350g(l)(3)(A) (providing that if the Secretary is investigating a "foodborne illness outbreak that is directly linked to a qualified facility" under the Act, and if the qualified facility is exempt from the hazard-analysis and risk-based preventive controls required under the Act, the Secretary may withdraw the facility's exemption after making certain safety-based determinations); 21 U.S.C. § 350i(f)(3)(A) (providing a similar provision for farms linked to outbreaks).

[27] Roland, *supra* note 6.

United States are subject to the Final PSR. These facilities are required to implement a food safety program to verify that their produce meets the standards.[28]

The seven provisions of the Final PSR establish a set of science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. The agricultural water provision (AWP) is summarized in Section IV. Also detailed are the studies and references[29] FDA used to justify their responses to stakeholder comments on the proposed Produce Safety Rule.[30]

II. PROVISION: AGRICULTURAL WATER

The AWP defines what is meant by water used in agriculture and requires that it must be safe and of adequate sanitary quality for its intended use. The AWP addresses three substantive issues. First, it establishes inspection and maintenance requirements related to water use, sources, and distribution systems associated with growing, harvesting, packing, and holding produce. Second, the water provision creates testing, treatment, and monitoring requirements including a set of specific standards designed to establish and to maintain microbial safety. Third, the AWP sets recordkeeping requirements for six criteria: inspection, including the water testing and treatment results; scientific data collection and other information to support microbial die-off and removal rates; time intervals to allow for microbial die-off; microbial treatments applied; alternative testing and treatment approaches; and corrective actions that are taken including any alternative approaches that may have been used.[31]

The provisions are reviewed in light of stakeholder comments. These comments covered five key themes: (A) the microbial indicator for fecal contamination; (B) the testing of water sources; (C) the microbial decay rate; (D) the wash water temperature; and (E) the treatment of contaminated water. Addressed below are each of the comment themes and FDA responses. Often, FDA responses consisted of a statement indicating that the Final PSR is based on appropriate scientific sources, a reference to additional sources such as supplemental notices, and/or revisions to the Final PSR. In some cases, FDA responses were simply an agreement or disagreement with the stakeholder comment.

A. Microbial Indicator

Stakeholders questioned FDA's proposed requirement (§ 112.44) to use generic *Escherichia coli*, a broad category of "*E. coli*" bacteria, as the indicator of microbial water quality because its detection does not necessarily indicate the

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[28] Drew and Clydesdale, *supra* note 4; Foreign governments may request a variance from one or more of the standards in the Produce Rule if they can demonstrate that they are able to provide the same level of public health protection as the requirements. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Final Rule, 80 Fed. Reg. 228. (November 27, 2015), *supra* note 11.

[29] We define "references" as published books or other documents that compile various sources of information that are generally regarded as scientific.

[30] All documents in the References section of the Final PSR were analyzed to determine if they fit the definition of "references" for the purpose of this paper. These peer-reviewed studies and books were then compiled in a spreadsheet and categorized by study purpose, study findings, FDA's claims made in the Final PSR, and study outcomes related to FDA's claims.

[31] 21 C.F.R. §§ 112.41–112.50.

presence of certain bacterial and non-bacterial pathogens. FDA agreed, but also stated that failure to detect an indicator does not guarantee pathogens are absent. Support for this statement came from a literature review showing a frequent discrepancy between indicator bacteria and pathogen concentrations due to the ubiquitousness of traditional fecal bacteria.[32] A study highlighting this point found that generic *E. coli* from watershed samples, taken in a produce farming region of California, was a poor indicator of *E. coli* 0157. This lack of detection was due to the fact that individual sample sites did not contain a significant number of *E. coli* 0157 cells to correlate with the presence of generic *E. coli*.[33,34]

FDA explained that in addition to generic *E. coli*, several indicators have been used to predict the presence of fecal pollution including total coliforms, fecal coliforms, enterococci, and coliphages. However, there have been varying degrees of success in the effectiveness of these other indicators. While FDA did not discuss enterococci and coliphages, FDA stated that neither total nor fecal coliforms serve as a reliable indicator of fecal contamination because many pathogenic sub-species are ubiquitous.[35,36,37] Two literature reviews supported this determination. Both reviews showed that many total coliforms[38] and fecal coliforms[39] are capable of growth in both the broader biophysical environment and in drinking water distribution systems.

Furthermore, many sub-species like the coliform *Klebsiella* are naturally present.[40,41] In a study of beach water,[42] 82 percent of bacterial isolates from water samples were confirmed to be *E. coli* and 16 percent were identified as other fecal coliforms. These findings demonstrate that *E. coli* is a better indicator of fecal pollution than fecal coliforms. Additionally, biochemical testing produced a wide

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[32] Suresh D. Pillai & Katherine G. McElhany, *Prevalence and Fate of Gut-Associated Human Pathogens in the Environment*, *in* THE FECAL BACTERIA 217, 217–240 (Michael J. Sadowsky & Richard L. Whitman eds., 2011).

[33] Approximately 1000 EcO157 isolates obtained from cultures of more than 100 individual samples were typed using Multi-Locus Variable-number-tandem-repeat Analysis (MLVA) to assist in identifying the potential fate and transport of the pathogen.

[34] Michael Cooley et al., *Incidence and Tracking of Escherichia Coli O157:H7 in a Major Produce Production Region in California*, 2 PLOS ONE (2007).

[35] H. Leclerc et al., *Advances in the Bacteriology of the Coliform Group: Their Suitability as Markers of Microbial Water Safety*, 55 ANN. REV. MICROBIOLOGY 201 (2001).

[36] Pam Tallon et al., *Microbial Indicators of Faecal Contamination in Water: A Current Perspective*, 166 WATER, AIR, & SOIL POLLUTION 139 (2005).

[37] Sandra L. McLellan, Annette D. Daniels, & Alissa K. Salmore, *Clonal Populations of Thermotolerant Enterobacteriaceae in Recreational Water and Their Potential Interference with Fecal Escherichia coli Counts*, 67 APPLIED ENVTL MICROBIOLOGY 4934 (2001).

[38] Defined as all facultative anaerobic, gram-negative, non-spore-forming, oxidase-negative, rod-shaped bacteria that ferment lactose to acid and gas within 48 h at 35 ◦C or members of Enterobacteriaceae which are β-galactosidase positive. AMERICAN PUBLIC HEALTH ASSOCIATION ET AL., STANDARD METHODS FOR THE EXAMINATION OF WATER AND WASTEWATER, (Lenore S. Clescerl et al. eds., 20th ed. 1998).

[39] Defined as coliforms that produce gas in EC broth at 44.5±0.2 ◦C within 24±2 h (APHA, 1998).

[40] Leclerc et al, *supra* note 35, at 221.

[41] Tallon et al., *supra* note 36.

[42] In this study, bacterial strains were isolated from beach water samples using the EPA method for *E. coli* enumeration and analyzed by pulsed-field gel electrophoresis (PFGE). McLellan et al., *supra* note 37, at 4934.

range of pulsed-field gel electrophoresis (PFGE)[43] patterns similar to the patterns found in *E. coli* isolates from known host sources.[44,45] *Klebsiella*, *Citrobacter*, and *Enterobacter* share characteristics with fecal coliforms such that they may falsely increase fecal indicator levels due to environmental replication. Moreover, coliform bacteria may originate from soil and vegetation, as well as other aquatic environments unrelated to fecal pollution.[46] In sum, FDA explained that generic *E. coli* is a member of both the coliform and fecal coliform groups, and it has been shown to be the coliform most consistently associated with fecal contamination.[47,48,49]

Two key studies formed the basis of FDA response to questions about the use of generic *E. coli* as an indicator of fecal contamination, both of which show that the presence of indicators does not always guarantee the presence of pathogens. One study involved in-mill water and external effluent treatment systems of seven typical Canadian pulp and paper mills.[50] With the exception of an operation that disinfected their input water, the mills sampled did not have sewage input, yet all samples supported the growth of numerous coliforms and the fecal indicator organism *E. coli*. Following disinfection, viable enteric bacteria were detected in all of the mills tested. The study investigators claimed that pulp-paper water systems were similar to produce water systems in that both should contain coliforms and indicator organisms while having no fecal input.[51] The second study evaluated Bifidobacterium spp. as a potential fecal contamination indicator in a Puerto Rican rainforest watershed.[52] Investigators found that all viable bacteria counts were related to the nutrient levels, regardless of the contaminants present at the sample site. The implication is that coliforms can become "normal" flora in tropical environments. Most importantly, these findings suggest that coliforms are a poor indicator of fecal contamination.[53]

B. Ground and Surface Water Testing

The Final PSR (§ 112.42) requires producers to test the entire agricultural water system under their control. In particular, §§ 112.44 & 112.46 direct growers to meet the requirements of a geometric mean of 126 or less colony forming units (CFU) of

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43 Pulsed field gel electrophoresis; McLellan et al., *supra* note 37, at 4937.

44 McLellan et al., *supra* note 37.

45 Charles P. Gerba, *The Role of Water and Water Testing in Produce Safety*, *in* MICROBIAL SAFETY OF FRESH PRODUCE 129 (Xuetong Fan et al. eds., 2009), http://onlinelibrary.wiley.com/doi/10.1002/9781444319347.ch7/summary (last visited Apr 26, 2016).

46 *Id.*; Tallon et al., *supra* note 36.

47 Tallon et al., *supra* note 36.

48 Francisco Diez-Gonzalez, *Fecal Bacteria and Foods*, in THE FECAL BACTERIA 275 (Michael J. Sadowsky & Richard L. Whitman eds., 2011), http://www.asmscience.org/content/book/10.1128/9781555816865.ch12 (last visited Apr 26, 2016).

49 Gerba, *supra* note 45, at 1328.

50 Francis Gauthier & Frederick Archibald, *The Ecology of "fecal indicator" Bacteria Commonly Found in Pulp and Paper Mill Water Systems*, 35 WATER RES. 2207, 2028 (2001).

51 *Id*.

52 Martha Carrillo et al., *Survival and Enumeration of the Fecal Indicators Bifidobacterium adolescentis and Escherichia coli in a Tropical Rain Forest Watershed*, 50 APPLIED ENVTL. MICROBIOLOGY 468 (1985).

53 *Id*. at 475.

generic *E. coli* per 100 mL of water, and a statistical threshold of samples at 410 CFU or less of generic *E. coli* in 100 mL of water. Some stakeholders questioned the feasibility and the frequency of water sampling for crops with different growing seasons, while others requested the freedom to design their own *E. coli* water-sampling program.

In response to these comments, FDA addressed several sampling challenges—frequency, location, persistence, and transport—that influence feasibility. The reviews cited support for the notion that *E. coli* detection methods are rapid, accurate, specific, and sensitive.[54,55,56] FDA defended its claim with both a reference document and a study showing that sampling frequency and location relative to the source of contamination can affect the performance of generic *E. coli* as a fecal indicator.[57,58] The first investigation found that detection of generic *E. coli* can be difficult because water masses move past their original sampling site, thus indicator concentrations at a single point may vary.[59] The second, which focused on Kentucky watersheds, determined that monthly sampling can be used to accurately assess the extent and variability of fecal contamination.[60,61]

FDA noted two additional points associated with water testing: *E. coli* may take different paths in different watersheds and *E. coli* may escape detection when they settle into sediments, sediments that then act as reservoirs.[62,63,64,65] Depending on the sampling location, bacteria in freshwater sediments may not be detected.[66] One reason for the lack of detection is stream re-suspension. If sediment-borne organisms are not distributed throughout the entire water column, samples taken in any one place may not represent the full column. In addition, sampling an entire water

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[54] Tallon et al., *supra* note 36, at 141.

[55] *See generally,* Leclerc et al., *supra* note 35.

[56] *See generally,* Diez-Gonzalez, *supra* note 48.

[57] NAT'L RESEARCH COUNCIL, INDICATORS FOR WATERBORNE PATHOGENS, (2004), http://www.nap.edu/catalog/11010 (last visited May 5, 2016).

[58] *See generally,* J. M. Howell et al., *Fecal Bacteria in Agricultural Waters of the Bluegrass Region of Kentucky*, J. ENVTL QUALITY 411 (1995).

[59] NAT'L RESEARCH COUNCIL, *supra* note 57, at 174.

[60] Water quality variation due to flow dynamics impact how frequently samples should be taken. Sampling location is also important because "fecal contamination in agricultural water reflects complex interactions affecting the survival, infiltration, and movement of . . . organisms in soil, water, and sediment." (Howell et al., *supra* note 60, at 412).

[61] Howell, *supra* note 58.

[62] Pillai & McElhany, *supra* note 32, at 231.

[63] A. Garzio-Hadzick et al., *Survival of manure-borne E. coli in streambed sediment: effects of temperature and sediment properties*, 44 WATER RES. 2753, 2754 (2010).

[64] Richard L. Whitman et al., *Physical and biological factors influencing environmental sources of fecal indicator bacteria in surface water*, *in* THE FECAL BACTERIA 111, 114-14 (Michael K. Sadowsky & Richard L. Whitman eds., 2011) http://www.asmscience.org/content/book/10.1128/9781555816865.ch06 (last visited June 11, 2017).

[65] Y.A. Pachepsky & D.R. Shelton, *Escherichia Coli* and Fecal Coliforms in Freshwater and Estuarine Sediments , 41 CRITICAL REV. IN ENVTL SCI. AND TECH. 1067, 1068 http://www.tandfonline.com/doi/abs/10.1080/10643380903392718#.Vx_VnPkrLIU (last visited Apr 26, 2016).

[66] Whitman et al., *supra* note 64.

column is highly impractical.[67] Another study tested the survivability of *E. coli* in a manure contaminated streambed to determine if it was affected by the organic carbon content.[68] It was found that *E. coli* survived in the sediments much longer than the overlaying water.[69]

Comments regarding the frequency for testing untreated surface water were quite critical stating that it is overly complicated, burdensome, lacks scientific justification, is a statistical construct, does not take into consideration site-specific variables of surface waters, and is not sufficiently flexible. Further, some argued that the time and location of sampling are more important than the number of samples. FDA explained their position and underlying statistical analysis in a self-authored reference document that accompanied the supplemental notice.[70] The document focused on the use of a rolling approach for calculating the microbial water quality profile. This "rolling approach" requires producers to collect initial samples (4 for groundwater, 20 for surface water), and then sample annually, as necessary, to create a dataset that retains the same number of total samples (1 for groundwater, 5 for surface water) on a yearly basis.[71]

Several comments supported a greater testing frequency for untreated surface water as compared to untreated groundwater sources used for the same purposes, while others suggested that there is no difference between the two. FDA responded by stating that groundwater is less likely to contain microorganisms due to the soil's natural filtering mechanism.[72] FDA recognized that groundwater can still be contaminated if wells are inadequately constructed, poorly maintained, improperly located (e.g., near extensive livestock production, near fields where raw manure is applied), and/or draw water from a contaminated aquifer.[73,74,75,76,77] For example, agricultural runoff from pastures often contains fecal bacteria. Subsurface transport of bacteria to shallow springs and wells is a concern in areas where groundwater is utilized as drinking water.[78,79] A study in New Zealand, which has an agro-ecological

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[67] Pachepsky & Shelton, *supra* note 65.

[68] Indigenous *E. coli* populations in stream sediments ranged from 10^1 to 10^3 MPN/g, while approximately 10^3 manure-borne *E. coli* MPN/g were added by inoculation.

[69] Garzio-Hadzick et al., *supra* note 63, at 2753.

[70] J Bowers, MEMORANDUM TO THE FILE - MINIMUM SAMPLE SIZE FOR ROLLING CALCULATION OF MICROBIAL WATER QUALITY PROFILE OF SURFACE WATER SOURCES TO BE USED FOR AGRICULTURAL WATER (2015).

[71] 21 C.F.R. § 112.46.

[72] Gerba, *supra* note 45.

[73] Howell, *supra* note 58.

[74] Murray Close et al., *Microbial groundwater quality and its health implications for a border-strip irrigated dairy farm catchment, South Island, New Zealand*, 6 J. WATER HEALTH 83, 84 (2008).

[75] C. Leifert et al., *Control of enteric pathogens in ready-to-eat vegetable crops in organic and "low input" production systems: a HACCP-based approach*, 105 J. APPLIED MICROBIOLOGY 931, 944 (2008).

[76] Richard J. Gelting et al., *Irrigation water issues potentially related to the 2006 multistate E. coli O157:H7 outbreak associated with spinach*, 98 AGRIC. WATER MGMT. 1395, 1397 (2011).

[77] Richard J. Gelting & Mansoor A. Baloch, *The food-water nexus: irrigation water quality, risks to food safety, and the need for a systems-based preventive approach*, 75 J. ENVTL. HEALTH 40, 40 (2012).

[78] Howell, *supra* note 58, at 411.

[79] Leifert et al., *supra* note 75.

environment similar to that found on the U.S. western and southern borders, evaluated the leaching of *E. coli* and *Campylobacter* from intensive dairying and border-strip irrigation. Groundwater samples were collected over a three-year period, mostly during the irrigation season, with 75 percent found to contain *E. coli*.[80,81]

Another study examined the environmental factors related to the 2006 spinach outbreak. Analysis of available data suggested that both the depth of the groundwater[82] and the surface and groundwater interactions may pose a risk to ready-to-eat crops such as spinach. Other potential sources of contamination include surface runoff, well construction, and direct or indirect application of irrigation water to crops.[83] In the spinach case, CDC and California Emergency Response Team investigators found that the outbreak was most likely due to the use of contaminated irrigation water. The source of this contamination was thought to have been surface water recharge of the groundwater that was used for irrigation.[84] Nevertheless, FDA concluded that surface water sources are inherently subject to a greater potential for contamination than well-maintained groundwater sources. Therefore, when both irrigation water source types are used under § 112.44(b), fewer groundwater tests are required compared to surface water.

C. Microbial Decay Rate

If agricultural water does not meet the requirements of § 112.44, producers may apply a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day to meet the standards. One comment requested flexibility to the standard in § 112.45(b)(1)(i) so as to make possible the application of a 0.5 log per day die-off rate on an hourly rather than a daily basis. FDA stated that there is little evidence to support a modification. As the literature indicates, decay constants have been found to vary within the 24 hour cycle, depending on climate and other conditions such as plant age, water application rate, time of inoculation, and presence of other natural flora.[85,86,87,88] FDA cited four studies of leafy greens to support their position on variable decay rates. First, it was found that the consumption risk was

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[80] Close et al., *supra* note 74.

[81] *Campylobacter* was identified in twelve percent of samples.

[82] Winter rain is stored in reservoirs and then released during the dry summer season to recharge aquifers used for irrigation. Analysis of the farm watershed system indicated that pathogens in surface water could have reached wells on the farm and contaminated irrigation water. During the growing season, groundwater levels dropped below the level of the San Benito River, allowing surface water to interact with groundwater on the farm.

[83] Gelting & Baloch, *supra* note 77, at 1396.

[84] *Id.* at 40.

[85] S. R. Petterson, N. J. Ashbolt & A. Sharma, *Microbial risks from wastewater irrigation of salad crops: a screening-level risk assessment*, 73 WATER ENVTL. RES. 667 (2001).

[86] J. M. Fonseca et al., *Escherichia coli survival in lettuce fields following its introduction through different irrigation systems*, 110 J. APPLIED MICROBIOLOGY 893–902 (2011).

[87] Anne-Laure Moyne et al., *Fate of Escherichia coli O157:H7 in field-inoculated lettuce*, 28 INT'L J. OF FOOD MICROBIOLOGY 1417 (2011).

[88] J. D. Wood et al., *Population dynamics of Escherichia coli inoculated by irrigation into the phyllosphere of spinach grown under commercial production conditions*, 143 INT'L J. OF FOOD MICROBIOLOGY 198 (2010).

high in cases associated with secondary-treated wastewater irrigation of lettuce.[89,90,91] Second, the survival rates of two *E. coli* strains, following leaf and soil irrigation of spinach, decreased over time.[92,93,94] Third, *E. coli* survived longer after sprinkler irrigation than subsurface drip or surface furrow irrigation.[95,96,97,98] Finally, drip and furrow irrigation had no effect on the persistence of *E. coli* O157:H7 on lettuce.

D. Wash Water Temperature

Section 112.48(c) of the Final PSR requires that producers maintain and monitor water used during harvesting, packing, and holding at temperatures appropriate for the commodity and operation. Some stakeholders believe that produce wash water should be warmer than the produce, while others question this assertion. FDA stated that when there is a certain degree of wash water temperature difference compared to the produce, it may influence the processes leading to infiltration of microorganisms. The QAR notes that this type of infiltration has been demonstrated in apples,[99] oranges,[100] tomatoes,[101,102] and mangoes.[103,104] The first cited study assessed the extent and location of *E. coli* O157:H7 contamination in four room temperature and refrigerated apple varieties subjected to immersion in cold *E. coli* inoculated peptone

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[89] If the viral rate of decay on the lettuce crop follows a first-order rate expression, then the decay coefficient is the slope of the linear regression line on a log scale versus time.

[90] Viral decay constants varied up to five logs on single days since last irrigation.

[91] Petterson et al., *supra* note 85.

[92] Various *E. coli* strains were applied at rates of 10^4 to 10^7 cfu/100ml to the spinach plants (secondary-growth). Culturable *E. coli* were recovered from plants up to six days post-inoculation.

[93] *E. coli* decay constants varied 2. 5-3 logs within a 24-hour period at one, two, and three days post inoculation.

[94] Wood et al., *supra* note 88.

[95] Overhead sprinkler, subsurface drip, and surface furrow irrigation methods were tested.

[96] In two trials, *E. coli* strains were injected into the water stream of the different irrigation systems to determine survival in the field. Results showed that product samples were positive for *E. coli* for up to seven days when using sprinkler irrigation, while only one product sample was found positive for *E. coli* when using other irrigation methods.

[97] It found decay constants in a twenty-four hour period were different for the inner and outer portion of lettuce when irrigated with the sprinkler.

[98] Fonseca et al., *supra* note 86.

[99] R. L. Buchanan et al., *Contamination of intact apples after immersion in an aqueous environment containing Escherichia coli O157:H7*, 62 INT'L J. OF FOOD PROTECTION 444 (1999).

[100] R. Merker, *Preliminary experiments on the effect of temperature differences on dye uptake by oranges and grapefruit*, (1999), http://agris.fao.org/agris-search/search.do?recordID=US201300053379 (last visited Apr 27, 2016).

[101] Jerry A. Bartz, *Infiltration of Tomatoes by Aqueous Bacterial Suspensions*, 71 PHYTOPATHOLOGY 515 (1981).

[102] J. A. Bartz, *Potential for Postharvest Disease in Tomato Fruit Infiltrated with Chlorinated Water*, 72 PLANT DISEASE 9 (1988).

[103] Ana Lucia Penteado et al., *Evidence of Salmonella Internalization Into Fresh Mangos During Simulated Postharvest Insect Disinfestation Procedures*, 67 J. OF FOOD PROTECTION 181 (2004).

[104] Sumathi Sivapalasingam et al., *A Multistate Outbreak of Salmonella Enterica Serotype Newport Infection Linked to Mango Consumption: Impact of Water-Dip Disinfestation Technology*, 37 CLINICAL INFECTIOUS DISEASE 1585 (2003).

water.[105] When immersed in cold water, warm fruit was more likely to take up the pathogen than cold fruit.[106] In a similar study, tomatoes were immersed in various suspensions with differing bacteria[107] and a negative suspension/fruit temperature differential. In general, weight increases were correlated with bacterial infiltration.[108,109]

In December 1999, there was a nationwide increase in *Salmonella* serotype Newport infections due to tainted mangoes from a single Brazilian farm. In this case, hot water was used as a treatment for fruit flies and it was identified as the point of contamination.[110,111] Immature and ripened mangos were positive for *Salmonella* internalization at a frequency of 80 percent and 87 percent, respectively.[112] This study supports FDA's position that infiltration of hot water containing pathogens could play a role in a produce outbreak.

Other studies demonstrated that pathogen infiltration can occur without a temperature differential.[113,114] For example, a different study of tomatoes found factors such as the variety and the time delay between stem removal and water immersion to have a significant impact on the frequency and population of internalized *Salmonella* spp.[115] However, the temperature differential had no significant effect on the incidence of *S.* enterica internalization.[116] Another study examined orange and grapefruit water-immersed dye uptake finding some evidence of low levels of uptake in grapefruit when there was no temperature differential. Yet, the authors also suggested that infiltration of water and dye can occur into an intact

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[105] Containing approximately $3x10^7$ CFU/ml *E. Coli* O157:H7.

[106] Buchanan et al., *supra* note 99.

[107] *S. marcesens, Erwinia carotovora*, *Pseudomonas marginalis,* or *P. aeruginosa*.

[108] The marker bacterium was isolated from fruit subject to negative pressure differential, with more isolated from fruits that gained more water weight.

[109] Bartz, *supra* note 101.

[110] Sivapalasingam et al., *supra* note 104.

[111] A simulation was conducted to evaluate this treatment and to assess whether this process promotes internalization of *Salmonella* into mangos. Dye internalization potential was determined: untreated domestically grown immature and ripened Tommy Atkins variety mangos were immersed in water at 47 degrees C for 90 min and then immersed in 21 degrees C water containing blue dye for 10 min. and the experiment was repeated using 21 degrees C water containing 10^7 CFU/ml *Salmonella* Enteritidis expressing constitutive green fluorescent protein. Fruit was then stored at 10, 20, or 30 degrees C for up to 1one1 week.

[112] Penteado et al., *supra* note 103.

[113] R. Merker, *Preliminary Experiments on the Effect of Temperature Differences on Dye Uptake by Oranges and Grapefruit*, (1999), http://agris.fao.org/agris-search/search.do?recordID=US201300053379 (last visited Apr 27, 2016).

[114] Xiaodong Xia et al., *Effects of Tomato Variety, Temperature Differential, and Post-Stem Removal Time on Internalization of Salmonella Enterica Serovar Thompson in Tomatoes*, 75 J. OF FOOD PROTECTION 297 (2012).

[115] Different tomato varieties, temperature differentials between tomato and bacteria suspension (-5.6, 0, and 5.6 °C), and post-stem removal times were evaluated for their effects on *S. enterica* internalization. Mature green tomatoes at 32.2°C were immersed in water containing approximately 10^6 CFU/ml *S.* enterica. The incidence and density of internalized cells were determined by culture enrichment and most-probable-number methods, respectively.

[116] Xia et al., *supra* note 114.

fruit when the temperature differential between fruit and water favors uptake.[117] Regardless of the conflicting studies, the final version of § 112.48(c) requires water temperature to be determined by the producer and to be considered appropriate for the commodity and operation. The time and depth of submersion and the method's adequacy in minimizing the potential for infiltration of pathogenic microorganisms must also be considered.

E. Water Treatment

When agricultural water does not meet the microbial quality criterion (§ 112.44(a)), the Final PSR requires one of two approaches that a covered farm must take (§ 112.45(a)): using a different source of water; or re-inspecting the water system, making necessary changes to bring the water system into compliance, and testing to confirm that the changes were effective. Several stakeholder comments express concern about the potential for adverse environmental impacts from implementing the water treatment provisions in § 112.43, namely the application of antimicrobial pesticides to ground water and the chemical treatment of irrigation water.

FDA responded that failures in treatment systems are largely attributed to suboptimal particle removal and treatment malfunction.[118,119] A cited review and study of municipal water treatment supported FDA's position, indicating that if properly applied, current protocols are effective at eliminating pathogens from water. However, inadequate, interrupted, and intermittent treatments repeatedly have been associated with waterborne disease outbreaks.[120,121] Water treatment failure may also occur from equipment malfunction and microbial pollution of reservoirs and local networks.[122]

Several comments requested additional instruction and examples regarding how to comply with the AWP. Citing three articles,[123,124,125] FDA provided an example of an effective orange post-harvest sanitation program using a chlorine-based wash,[126] but

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[117] Merker, *supra* note 113.

[118] Kelly A. Reynolds et al., *Risk of Waterborne Illness Via Drinking Water in the United States*, 192 REVS. ENVTL. CONTAMINATION & TOXICOLOGY 117 (2008).

[119] T. Westrell et al., *A Theoretical Approach to Assess Microbial Risks Due to Failures in Drinking Water Systems*, 13 INT'L J. ENVTL. HEALTH RES. 181 (2003).

[120] Contamination levels are affected by the number of pathogens in the source water, the age of the distribution system, and the quality of the delivered water, as well as climatic events.

[121] Reynolds et al., *supra* note 118, at 149.

[122] Westrell et al., *supra* note 119, at 192–93.

[123] Trevor Suslow, POSTHARVEST CHLORINATION BASIC PROPERTIES AND KEY POINTS FOR EFFECTIVE DISINFECTION (1997), http://ucfoodsafety.ucdavis.edu/files/26414.pdf (last visited Apr 26, 2016).

[124] Trevor Suslow, WATER DISINFECTION: A PRACTICAL APPROACH TO CALCULATING DOSE VALUES FOR PREHARVEST AND POSTHARVEST APPLICATIONS (2001), http://furrowpump.com/water-disinfection-a-practical-approach-to-calculating-dose-values-for-preharvest-and-postharvest-applications/ (last visited Apr 26, 2016).

[125] M. A. Ritenour et al., CHLORINE USE IN PRODUCE PACKING LINES (2014), https://edis.ifas.ufl.edu/pdffiles/CH/CH16000.pdf (last visited June 6, 2017).

[126] The antimicrobial activity of chlorine compounds depends on the amount of hypochlorous acid present in the water after the treatment is applied.

also explained that the water temperature and pH modifications, and/or allowing time for microbial die-off between last irrigation and harvest, could also be used successfully. Also noted were parameters (e.g., water temperature, amount of antimicrobial substances used) that require continuous monitoring and adjustment as hypochlorite activity is reduced by organic material (e.g., soil, plant debris), and it is ineffective if the pH values are outside its normal range (i.e., pH 6.0-7.5).[127,128,129] In addition, as one commenter stated, there are several non-chemical treatments for agricultural water—mechanical (e.g., filtration) and physical (e.g., pesticide devices)—under examination. FDA acknowledged these possible alternatives indicating that there may, in fact, be other technologies that are effective, including several pesticide devices (e.g., filter units, ultraviolet light units, ozonator units), the use of reverse osmosis, and solar radiation.[130] In response, a revision to § 112.43(a) included some additional acceptable means of treating agricultural water to meet the relevant microbial quality criteria in § 112.44.

III. CHALLENGES TO IMPLEMENTATION

An endless number of access points between production and consumption complicates the prevention of microbial contamination along the produce supply chain. FDA considers the Final PSR to be a grand "food safety plan," designed to identify and mitigate said complication system-wide.[131] Focusing strictly on the water provision, the AWP addresses two key points—irrigation during growing and washing at harvest—where contamination is likely to occur at the farm level. Analysis of the standards within the provision finds that they are generally supported by scientific studies published in the peer-reviewed literature, and secondarily via microbial reference materials. Yet, there are notable questions about the science and gaps in the literature. Most problematic for both growers, and regulators charged with application of the Final PSR, are those areas in which uncertainty exists. In the proceeding sections, the science behind the AWP and associated uncertainty will be discussed.

A. Science

The use of "sound science" is the foundation of FSMA and its associated risk assessment.[132] Valid science used in rulemaking is publicly available, peer-reviewed work published in scientific journals or textbooks. FDA also includes proprietary research that is not open to review, evaluation, or use by supply chain actors, which are critical aspects in the "practice" of science. The context in which these proprietary studies are used is unclear. In addition, there is no information about

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[127] Suslow, *supra* note 123, at 2–4.

[128] Suslow, *supra* note 124.

[129] Ritenour, *supra* note 125.

[130] Mark A. Shannon et al., *Science and Technology for Water Purification in the Coming Decades*, 452 NATURE 301 (2008).

[131] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Red. 74,354, 74,358 (Nov. 27, 2015).

[132] *Id.* at 74,355.

FDA oversight of proprietary studies[133] or the ways in which FDA may have assessed these works for their scientific merit. For example, an FDA authored study examined the average variability among surface water sources. This project determined the sample size requirements for estimating microbial water quality profiles.[134] Since the FDA document was not peer-reviewed, and cannot be easily obtained,[135] its applicability for a scientist or a grower is unclear.

The practice of science also requires accurate application and representation of existing work. Yet, there were cases in which FDA used studies that did not necessarily support its assertion. For instance, the use of generic *E. coli* as a microbial standard is based on the EPA drinking water criteria, which might not translate to irrigation water.[136] In addition, several cited studies did not look at generic *E. coli* at all, but instead examined other pathogens, namely *Salmonella*. In the case of microbial die-off criteria (i.e., 0.5 log die off rate per day), a source FDA cited did not completely support the regulation, because the source failed to assess die-off rates over a 24-hour period.[137] Detailed in Section IV was the case of wash water temperature. FDA's concern was "pathogen uptake" during rinsing, but the cited study focused on dye uptake,[138] and it did not use water temperature as a variable. Another FDA claim recommended chlorine as a water treatment, yet the cited literature indicated that chlorine may enhance microbial infiltration.[139]

Second, there are gaps in the literature. Some commenters suggested that further research is warranted to fill the lacuna such as microbial die-off or removal rates associated with washing, harvest, and storage;[140] and determining water quality standards with greater precision should be required. FDA denied these stakeholder comments, citing the QAR. As noted in Section III, however, a QAR reviewer indicated that the incomplete microbial die-off data limited his or her ability to understand fully the processes involved in microbial contamination.[141] In addition, directly comparable studies appear to be lacking. For example, during the rulemaking, FDA drew on several studies conducted in agro-ecological regions and

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[133] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Correction, 78 Fed. Reg. 17,142, 17,143 (Mar. 20, 2013).

[134] Bowers, *supra* note 71.

[135] Efforts were made to search both the FDA database and Google for documents with this title. Academic search engines, including Westlaw, were also utilized without success. The only known way to access this document without a FOIA request is with the docket number FDA-2011-N-0921-18658. However, this docket number is not provided in the Reference section of the Final PSR. Simply searching for the title of the document on regulations.gov does not yield the correct document.

[136] Letter from Judith McGeary, Executive Director, Farm & Ranch Freedom Alliance, et al., to FDA (Dec. 15, 2014) http://farmandranchfreedom.org/wp-content/uploads/2014/12/FSMA-organizational-comments-PRODUCE-RULE-2014-Submitted.pdf.

[137] Moyne et al., *supra* note 87, at 1421.

[138] Merker, *supra* note 113.

[139] Bartz, *supra* note 101, at 517–18.

[140] "As noted in the supplemental notice, at this time, FDA is not establishing specific microbial die-off rate(s) between harvest and end of storage, or specific microbial removal rate(s) during postharvest activities such as commercial washing, because they do not have sufficient information to support the derivation of appropriate, broadly applicable, microbial die-off or reduction rate(s) for these purposes." Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74,354, 74,444 (Nov. 27, 2015).

[141] FDA, *supra* note 17.

in production environments[142] that may not be directly comparable to the dominant or relevant growing regions and/or commodity systems from which the US primarily sources its produce.[143] Another gap in the current body of research is that which addresses the question of scale. Organizations such as the Produce Marketing Association and the Food Marketing Institute argue that exempting farms based on revenue (see Section III) is not a scientific or risk-based approach as contamination may occur on any farm with unsafe practices.[144,145] A study of small-scale organic farms in Maryland illustrated this point when investigators found indicator organisms in their produce and water samples.[146,147]

B. Uncertainty

While FDA did not avoid any particular topic, the very large number and wide range of comments during the rulemaking process suggest a high level of uncertainty about the standards, many of which are tied to Final PSR *implementation*. Most of the comments related to the AWP fell into three categories: expertise, ambiguity, and data.When FDA responded to questions about an approach in the Final PSR, uncertainty appeared to be the underlying issue.

First, implementation of the AWP requires scientific expertise. For example, it is up to the producer to evaluate how often water sources ought to be tested and treated beyond the initial requirements, and to create a management system that ensures safe produce. Water testing itself requires a working knowledge of *E. coli* detection methods, aseptic sampling procedures, appropriate sample timing and location, pH and antimicrobial testing, and the ability to utilize geometric means and statistical threshold values for evaluating *E. coli* presence. Further complicating the matter, the AWP is in flux as FDA is currently reviewing ways to simplify the microbial agricultural water standards, recognizing that they "may be too complex to understand, translate, and implement."[148]

Expertise related to "on-the-ground" application of the standards is also required as stakeholders requested guidance on a number of issues. These issues included data sharing; inspection timing and sampling program design; reconciling regulatory or

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[142] Studies were conducted in New Zealand, Puerto Rico, Kentucky, and California, for example. Close et al., *supra* note 74; Carrillo et al., *supra* note 52; Howell et al., *supra* note 58; Cooley et al., *supra* note 34.

[143] It is important to note, however, that FSMA applies to imported produce, some of which may be grown and processed in tropical regions in which these studies took place.

[144]Samuel R. Wiseman, *The Implementation of the Food Safety Modernization Act and the Strength of the Sustainable Agriculture Movement*, 41 AM. J. L. & MEDICINE 259, 271 (2015).

[145] A key argument supporting the exemption is that an outbreak from a small business would have a minimal and relatively contained impact in contrast to an outbreak from a large-scale operation that would have large domestic implications.

[146] Aixia Xu et al., *Comparing the Microbiological Status of Pre- and Postharvest Produce from Small Organic Production*, 78 J. FOOD PROTECTION 1072 (2015).

[147] In a study of local foods, vegetables at California farmers markets were found to be positive for several strains of *Salmonella* and fecal coliforms. Fengguang Pan et al., *Cross-Sectional Survey of Indicator and Pathogenic Bacteria on Vegetables Sold from Asian Vendors at Farmers' Markets in Northern California*, 78 J. FOOD PROTECTION 602 (2015).

[148] FDA, FOOD SAFETY MODERNIZATION ACT (FSMA) - FDA CONSIDERING SIMPLIFYING AGRICULTURAL WATER STANDARDS (2017), https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm546089.htm (last visited Apr 1, 2017).

certification compliance (e.g., NOP certification, EPA pesticide use registration, state water treatment regulations); hazard identification (e.g., conditions likely to introduce known or foreseeable problem when water cannot be treated); and potential hazards of water decontamination (e.g., treatment causing pollutant discharge). In some cases, FDA referred the reader to other FDA or EPA authored documents.[149,150] Thus, while FDA responded to these questions, and often provided an assurance that the methods mentioned would comply with the AWP, it did not always provide science-based evidence in their response.[151]

Second, implementation requires *interpretation* of vague information. When the Final PSR was published, FDA did not have a clear picture of the on-farm application of the standards, and thus, had not developed guidance documents. Consequently, there were 650 comments requesting clarification of the central concept of the provision, the definition and identification of "agricultural water" (e.g., inclusion of pooled water in produce fields, identifying discrete sources, harvest related uses including packing and holding). Another 500 comments requested clarification of the sample timing standard. The Final PSR also included 326 instances in which producers were simply instructed to use measures that are "reasonably necessary" to prevent contamination. Currently, FDA permits growers to determine, with little guidance,[152] water temperature, adequate procedures to prevent contamination both pre- and post-treatment, and alternative measures. And, while FDA provided additional clarification for some standards (e.g., the EPA recreational water criteria, indicators of quality, sanitation assurance, criteria for specified purposes, alternative quality criteria), it did so without scientific justification.

A third point is that implementation requires access to generally accepted scientific data. There are several circumstances in which the AWP allows producers to use an "alternative" approach (e.g., microbial criteria, testing frequency, die-off rates). In these cases, an alternative is permitted when it is supported by adequate scientific data that illustrates effectiveness in providing the same level of public health protection as the method stated in the AWP. Yet, access to, and development of, an alternative will be difficult, particularly for small-scale and remote producers. As noted above, there are gaps in the literature. Of the literature that is available, a majority is published in publicly availably peer-reviewed journals, but retrieval

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[149] FDA, FINAL ENVIRONMENTAL IMPACT STATEMENT (EIS) FOR THE PROPOSED RULE: STANDARDS FOR GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION (2015), https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM470749.pdf.

[150] EPA, ABOUT PESTICIDE REGISTRATION (2015), https://www.epa.gov/pesticide-registration/about-pesticide-registration.

[151] For instance, one commenter expressed concern that treating water with antimicrobials would be considered a point source discharge of a pollutant and would make producers liable under the Clean Water Act. FDA referred the reader to the EIS (FINAL ENVIRONMENTAL IMPACT STATEMENT (EIS) FOR THE PROPOSED RULE: STANDARDS FOR GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION) for a detailed discussion of the potential environmental effects of the agricultural water provision.

[152] The current draft guidance published only applies to sprouts, which have more specific regulations. U.S. FOOD DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: COMPLIANCE WITH AND RECOMMENDATIONS FOR IMPLEMENTATION OF THE STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION FOR SPROUT OPERATIONS (2017), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm510578.htm (last visited Apr 1, 2017).

requires physical access to a research library and/or a credential to gain access remotely. Additionally, these studies are written for an academic audience, making them generally inaccessible to others without discipline specific expertise.

CONCLUSION

While some instances in the AWP were found to be weakly supported, analysis of stakeholder comments suggest that FDA did make a good faith effort to address thousands of comments, to provide assurances where possible, and to offer science-based rule modifications. Overall, the comments and responses illustrate that the application of FSMA is problematic for both growers and regulators. Our research found three policy implications that are specific to the science used to bolster the AWP. First, there are key gaps in the water safety research as it relates to on-farm production, and these gaps may cause ambiguity for both producers and regulators. Second, there are costs associated with implementing the science-based standards that may not be readily discernable to decision-makers. Third, there are concerns about the capacity of regulators to provide producers with adequate application guidance, and a lack of sufficient guidance, may put growers at an increased risk of non-compliance.[153,154]

As FDA acknowledged, further research on produce pathogen growth on farms is needed to support the Final PSR.[155] Also lacking is work on determining the origin, survival, and distribution of pathogens in an agro-ecological environment (i.e., pathogens from wild animals and livestock, from soil contamination, from post-harvest operations). This work ought to include, but not be limited to, questions about how pathogens transfer to, and reproduce on, produce; questions about the appropriate on-farm methods to reduce contamination; and questions about the number and prevalence of pathogenic cells remaining in contaminated produce at consumption.[156] Stakeholder questions about rule implementation were understandably difficult for FDA as the agency began with a deficit—FDA has not traditionally been involved in production agriculture—and many of the comments came from producers throughout the country, many of whom access and use agricultural water differently. These questions brought up a number of topics that require further investigation: ascertaining the effects of farm size and region on produce safety, determining how to describe the hurdles faced by growers of all sizes, and understanding how the relationship between production practices and crop type may influence contamination.

To supplement the science available, FDA will need access to investigators with expertise in production agriculture. Traditionally, scientific questions about agricultural production, water, and food safety have been addressed via competitive funding opportunities associated with the USDA (e.g., National Institute of Food and Agriculture (NIFA) Foundational Program grants). This funding is most commonly awarded to investigators at research universities (e.g., land grant institutions and

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153 *See* Nicholas R. Johnson & A. Bryan Endres, *Small Producers, Big Hurdles: Barriers Facing Producers of "Local Foods,"* 33 HAMLINE J. PUB. L. POL'Y 49, 68–77, 79–86, 99–122 (2012).

154 Kathryn A. Boys, *Food Product Liability Insurance: Implications for the Marketing of Specialty Crops*, 28 CHOICES, NO. 4, 1–4 (2013).

155 FDA, *supra* note 13.

156 *Id.*

agricultural experiment stations), regional laboratories (e.g., National Food Safety and Toxicology centers), and government agencies (i.e., USDA Agricultural Research Service). Going forward, FDA might create new opportunities through the National Science Foundation (NSF), work within the existing USDA funding structure, and/or collaborate directly with state Agricultural Experiment Stations, state Cooperative Extension Services, and state Departments of Agriculture. Additionally, FDA ought to develop a means for making publicly available any proprietary research used in rulemaking and implementation standards.

Not addressed, above (Section IV), were comments rooted in concerns of *equity*. The dominant concern among these comments was whether the financial cost of implementation is fair for small-scale farms, as it has been addressed elsewhere.[157] Others also note that regulations may increase the vulnerability of small farms should an outbreak occur because contamination may be more easily traced-back;[158] retailers, buyers, and institutional food providers have begun to require small farms to carry liability insurance;[159] and tort law has been used to hold producers liable when found negligent.[160] Nevertheless, with respect to retaining the notion of a science-based Final PSR, there is a dearth of studies examining small-scale farms *before* implementation. Such studies are necessary to determine whether the regulations have an impact on an entity's economic viability and public health more broadly.

Often overlooked in assessing food safety rules is that there is a "cost" in the "science" of the individual standards. For instance, implementation of the AWP will require water samples to be tested at certified labs that will undoubtedly charge user fees.[161] These labs are required to meet a range of scientific and technical standards for analysis[162] that may not be feasible for producers to meet on-farm, except the very largest corporate entities. Moreover, some costs are less visible; there will be a costly, and high, learning curve for the vast majority of producers because only very large-scale operations are likely to have dedicated food safety personnel. There will be costs in learning the details of the Final PSR and in understanding at least some of the underlying science including the associated jargon, techniques, and data.

Capacity in rule implementation is a third issue. While some growers[163] may already meet GAP and other buyer standards that have similar criteria to the agricultural water provision, this is not the case for most.[164] Growers of all sizes will need sufficient investment in education to mitigate a range of limitations in

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[157] Oldfield, *supra* note 4; Drew and Clydesdale, *supra* note 4; Strauss, *supra* note 5; Eads and Zwagerman, *supra* note 5; Fortin, *supra* note 5; Pouliot, *supra* note 7; Roland, *supra* note 6; Hassanein, *supra* note 8.

[158] Johnson & Endres, *supra* note 153, at 66.

[159] Boys, *supra* note 154, at 2.

[160] Johnson & Endres, *supra* note 153, at 117–20.

[161] Roland, *supra* note 6, at 140–44.

[162] 21 U.S.C. §§ 1.610–1.615, 1.641–1.645

[163] In a study of GAP certified farms in Vermont, it was found that they tended to be larger in acreage than non-certified farms. Sasha C. Marine et al., *Effect of Market Channel, Farm Scale, and Years in Production on Mid-Atlantic Vegetable Producers' Knowledge and Implementation of Good Agricultural Practices*, 59 FOOD CONTROL 128, 129 (2016).

[164] Maki Hatanaka, Carmen Bain & Lawrence Busch, *Third-party certification in the global agrifood system*, 30 FOOD POLICY 354–369 (2005).

knowledge and gaps in the accessible literature. One option is to seek out third-party training, which can exceed $400 per course/per individual,[165] a cost and commitment that will push some to pay for outside "experts."[166] Growers unable to "buy" scientific expertise will have few places to turn for guidance as state Departments of Agriculture lack funding and state Cooperative Extension programs are already overburdened.[167]

FDA is currently working on guidance documents intended to provide "user friendly" suggestions on how to meet some of the Final PSR requirements. Two points considered "high priority" are documents detailing the definition of "agricultural water" and sample timing.[168] Yet, the financial resources for assisting growers via research funding and direct assistance is unclear. FDA has begun to collaborate with NIFA to provide funding for food safety technical assistance, training, and education, and its 2017 objectives include increasing states' capacity for rule implementation. However, the expected budget across all key agencies and organizations is woefully lacking.[169] Potentially more problematic, at the time of this writing, is that President Trump has called for an 18 percent cut to FDA's budget.[170] In addition, the new Trump Administration has introduced a bill that is intended to strip regulations and hinder regulatory rulemaking, which food safety groups refer to as the "Filthy Food Act" and interpret as an intent to cut science from the regulatory process.[171]

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[165] *See*, *e.g.* Produce Safety Alliance, Upcoming Grower Trainings https://producesafetyalliance.cornell.edu/training/grower-training-courses/upcoming-grower-trainings (last visited Mar. 7, 2017).

[166] Similar examples include integrated pest management (IPM) scouts and crop consultants, as well as the use of soil testing laboratories.

[167] Mahdi M. Al-Kaisi et al., *Extension Agriculture and Natural Resources in the U.S. Midwest: A Review and Analysis of Challenges and Future Opportunities*, 44 NAT. SCI. EDUC. 26, 27, 29–30 (2015).

[168] U.S. GOV'T ACCOUNTABILITY OFFICE, FOOD SAFETY: FDA'S EFFORTS TO EVALUATE AND RESPOND TO BUSINESS CONCERNS REGARDING THE PRODUCE RULE, (Nov. 28, 2016) at 3 http://www.gao.gov/assets/690/681273.pdf..

[169] The National Association of State Departments of Agriculture (NASDA), for instance, has stated that it is unable to assist without significant federal funding. Barbara Glenn, NASDA LETTER TO SENATE APPROPRIATORS ON THE FY 17 PRESIDENT'S BUDGET AND FSMA IMPLEMENTATION (Mar. 1, 2016), http://www.nasda.org/Policy/filings/Letters/40009/41263.aspx.

[170] *Mixed News for Food Agencies in Trump's Budget*, FOODQUALITYNEWS.COM, (Mar. 20, 2017 12:37 GMT), http://www.foodqualitynews.com/Regulation-and-safety/Budget-User-fees-for-FDA-FSIS-survives-but-USDA-faces-cuts; Jason Huffman, *Trump wants cuts to USDA*, *FDA 2017 Funding,* POLITICO, (Mar. 28, 2017 10:00 AM), http://politi.co/2ouba0A (last visited Apr 2, 2017).

[171] Joe Whitworth, *Consumer Orgs Dub Regulation "Filthy Food Act"*, FOODQUALITYNEWS.COM, (Mar. 24, 2017), http://www.foodqualitynews.com/Regulation-and-safety/Groups-slam-Regulatory-Accountability-Act.