Economic Efficiency of Food Safety Modernization Act: Preventing Illnesses from Contaminated Water

Marziyeh Bahalou Horeh
Graduate Student
West Virginia University
mb0062@mix.wvu.edu

Levan Elbakidze
Associate Professor
West Virginia University
Levan.elbakidze@mail.wvu.edu

Selected paper prepared for presentation at the 2020 Agricultural & Applied Economics Association Annual Meeting, Kansas City, KS.

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Abstract

This paper provides a theoretical framework and a corresponding empirical analysis of food safety-related irrigation water quality regulatory standard under the Food Safety Modernization Act (FSMA). The stochastic mixed integer price endogenous partial equilibrium model with recourse is used to examine the optimal irrigation water quality regulatory standard under various scenarios of the foodborne illness harm values, costs of implementing the regulatory standard, costs of irrigation, and other key parameters. The study explicitly examines tradeoffs between improved food safety and costs of regulation, taking into account producer response to regulatory requirements, the effectiveness of the prevention strategy, and implications for welfare in terms of economic surplus. Lettuce industries in California and Arizona are considered as a case study. We find that expected prices of "Head" and "Leaf and Romaine" lettuce under the FSMA proposed regulatory standard increase by 0.98% and 1.38%, respectively relative to the solutions with no regulatory standard. The results show that if average cost per foodborne illness is $4,000, the regulatory standard does not pass the cost/benefit test. If the cost of illness increases to $10,000 per case, then the standard is cost effective unless implementation costs exceed $2 million.

Keywords: Food Safety Modernization Act; Partial equilibrium; Irrigation water quality.
JEL classification: D61, D78, Q11, Q18

1. Introduction

Food safety remains a major public health concern with significant implications for consumers as well as producers (Ollinger and Bovay, 2020; Bar and Zheng; 2019; Bellemare and Nguyen, 2018).[1] Despite the economic importance of foodborne disease management and the reoccurring illnesses related to consumption of fresh fruits and vegetables, there has been relatively little research that examines the economic efficiency of *ex ante* regulatory stringency aimed at preventing food contamination in fresh produce sector. Nevertheless, policies aimed at improving food safety and preventing foodborne illnesses continue to attract significant attention. For example, in response to numerous foodborne disease outbreaks, the Food Safety Modernization Act (FSMA) was introduced in 2011 to improve the nations' food safety by directing efforts towards prevention of foodborne illnesses with a particular focus on fresh fruits and vegetables.[2] The intent of the FSMA was to focus more on preventing food contamination related illnesses rather than reacting to those incidents after they occur. As part of the FSMA, the Food and Drug Administration (FDA, 2014) proposed preventative standards and guidelines for safe growing, harvesting, packing, and storage of fresh produce intended for human consumption without processing. According to FDA, agricultural water used during growing and harvest has the highest likelihood of introducing pathogens in fresh produce consumption. Therefore, reducing pathogens in irrigation water was proposed as a major component of foodborne disease prevention efforts (FDA, 2012).

In this paper, we develop an economic model for foodborne illness control that examines the effectiveness of *ex ante* efforts taking into account the effects on both consumers and producers in a stochastic environment. First, we provide a theoretical framework for examining irrigation water quality assurance efforts. Conditions for optimal regulatory stringency of the microbial water

[1] Centers for Disease Control and Prevention (CDC) announced an outbreak of *Escherichia Coli* (*E. coli*) in 2018 linked to romaine lettuce irrigated with contaminated water that affected 272 people in at least 16 states with 121 hospitalizations and 5 deaths (CDC, 2018). In April 2020, 51 reported cases of outbreak of *E. coli* with 3 people hospitalized linked to Clover Sprouts were announced. In January 2019 another *E. coli* outbreak was linked to romaine lettuce. There were 167 cases with 85 people hospitalized in this outbreak (CDC, 2020 and 2019)

[2] The final FSMA rule went into effect in 2016 (the U.S. Food and Drug Administration, 2020).

quality requirements are derived as a function of irrigation costs, costs of regulatory efforts, illness severity, and consumers' illness prevention efforts. Next, the optimality conditions are examined empirically using the lettuce market as a case study. The model is applied to the analysis of the *ex ante* regulatory standard for microbial quality of irrigation water and *ex post* required delays in harvest and storage when microbial quality standards are exceeded to allow for pathogen die-off as proposed by FDA.

Several studies have addressed the FSMA. Ferrier et al. (2018) estimate the price and welfare effects of the FSMA using an equilibrium-displacement model for 20 vegetables and 18 fruits. Their simulation results show that the FSMA increases farm and consumer prices by 1.46% and 0.49% for fruits respectively and 0.55% and 0.14% for vegetables, respectively. They also estimate that vegetable and fruit producers' welfare will decrease by 0.59% and 0.86% respectively because of the costs of implementing of the FSMA rules. Bovay and Sumner (2017) use an equilibrium-displacement model to study the long-run economic effects of the FSMA in the North American fresh-tomato industry. Assuming that implementation of the FSMA leads to less frequent foodborne outbreaks and greater demand for safer produce, they show that the wholesale tomato prices increase by up to 2.4% due to the implementation of the FSMA if demand for safer produce increases slightly relative to a scenario with more foodborne outbreaks and no FSMA. The results also indicate that the small farms are disadvantaged due to economies of scale in implementing the FSMA directives relative to larger farms.

Bovay (2017) uses an Inverse Almost Ideal Demand System to assess how adoption of collective food-safety standards by farmers in 2007 affected the demand for tomatoes in California and Florida. The results of the study do not support the hypothesis that food-safety policies have a positive impact on demand for fresh tomatoes. This study suggests that since demand is not likely to increase, growers' profits are likely to decline because increased costs due to the FSMA regulations are not offset by a rise in the output price.

Adalja and Lichtenberg (2018) use data from a national survey of fruit and vegetable growers and econometrically estimate the growers' cost of complying with the FSMA across farms of various sizes. The results demonstrate economies of scale in the costs of implementing required food safety practices (e.g. employee training, tool and equipment sanitation, etc.). Larger farms bear lower costs of implementation per acre. Focusing on a narrower geographic scope and particular crops, Lichtenberg and Page (2016) estimate the cost burden of adopting food safety practices like those required under the FSMA using data from a survey of 47 Mid-Atlantic tomato and leafy greens growers. The results show substantial economies of scale and a modest cost burden on farms of all sizes. They discuss that improvement in compliance with the FSMA for non-exempt and small farms that bear a large cost burden may be difficult. Bovay et al. (2018) use data from the 2012 Census of Agriculture to estimate the cost of the FSMA compliance by state, farm size, and commodity. Using FDA's cost of compliance estimates, they show that the annual cost of compliance, expressed in terms of percentage of total sales, is higher for smaller size farms.

To our knowledge this paper is the first attempt to examine the food safety-related irrigation water quality regulatory standards as a major component of the FSMA. The model builds on a unique framework that integrates a dose-response formulation consistent with the framework proposed by Lichtenberg (2010) and a stochastic partial equilibrium framework that can be applied in similar studies of food safety regulations. We contribute to prior literature with an explicit analysis of irrigation water quality control as an *ex ante* strategy for foodborne disease mitigation taking into account costs imposed on producers as well as consumers.

Contaminated irrigation water can lead to illness if it comes in contact with the edible portions of vegetables or fruits that are consumed fresh. To address this risk, FDA proposed rules that require periodic testing of irrigation water and restrict the use of water that exceeds the maximum allowable amount of indicator microorganisms (*Generic E. coli*). *Generic E. coli* is found in more than 90% of human and animal feces as well as in non-fecal sources (FDA, 2014). Many irrigation water sources in the western U.S. exceed the standards of *E. coli* set by the FDA guidelines (Dadoly and Michie, 2010).

According to the FDA guidelines, if a) the statistical threshold value (STV) of *E. coli* content exceeds 410 colony forming units (CFU) or b) moving geometric mean (GM) exceeds 126 CFU per 100 ml of water from any 5 consecutive samples of surface water or 1 sample of ground water, then the irrigators have to either stop using water from the contaminated sources (unless treated), or extend the storage period and/or delay harvest to allow for microbial die-off (FDA, 2014). The producers can extend the pre-sale period for up to four days. Produce that is not in compliance even after four additional days of microbial die-off, based on the 0.5 log rate reduction of CFUs per day, is to be discarded.

The empirical analysis in this paper relies on a stochastic two stage price endogenous partial equilibrium model with recourse. County level planting, irrigation, and delay decisions are optimized with national supply constrained by aggregate county level production in the US plus net imports. The objective is to maximize consumer and producer surplus minus aggregate costs *of E. coli*-related illness incidents and costs of prevention efforts. The constraints include demand and supply balance, stochastic water quality equations, yield and irrigation relationships, harvest and storage delay constraints reflecting STV and GM standards, and illness dose-response specifications.

The two-stage model explicitly examines the tradeoffs between improved food safety and costs of regulation, taking into account producer response to regulatory requirements in terms of planting and irrigation decisions, the costs and effectiveness of the prevention activities, and the implications for producer and consumer surpluses.[3] In the first stage, before the stochastic *E. coli* content in irrigation water is determined, the producers make lettuce planting and irrigation decisions. In the second stage, harvesting and storage decisions are made subject to the FSMA regulations pertaining to acceptable microbial quality of irrigation water.

The empirical results are consistent with the theoretical analysis and show that expected prices of “Head” and “Leaf and Romaine” lettuce increase by 0.98% and 1.38%, respectively relative to the solutions with no regulatory standard and more lettuce-related illnesses. We also find that considering the consumers and producers surplus impacts, the proposed water quality standard is excessively stringent. Also, the results show that if the cost of foodborne illness is \$4,000, the FSMA regulatory standard does not pass cost/benefit test. If the cost of illness increases to \$10,000 per case, the regulatory standard passes this test unless implementation costs exceed \$2 million.

2. Theoretical Model

The theoretical framework is consistent with a cost minimization balancing framework (Elbakidze and McCarl 2006, Hagerman et al. 2015). Conceptually, the economically efficient policy minimizes total costs comprised of *ex ante* costs of prevention and preparedness and *ex posts* costs of response to and damages from stochastic contamination events. *Ex ante* costs refer to costs of activities and policies implemented before the outbreak with the goals of preventing or

[3] In contrast, the FDA’s cost/benefit analysis did not include consumer and producer welfare implications (FDA, 2014).

minimizing the risks of foodborne disease outbreaks and/or enhancing the capacity and effectiveness of response activities after the outbreak. These costs include direct implementation costs, like costs of water sampling and testing, as well as losses in consumer and producer surpluses as a result of potential decrease in supplies and increase in prices due to higher costs of production. *Ex post* costs refer to losses due to foodborne illnesses including medical treatment costs as well as producer and consumer surplus losses.

For relatively less stringent *ex ante* regulation with high levels of maximum allowable *E. coli* concentration in irrigation water, the probability and/or severity of foodborne disease outbreaks is relatively high corresponding to high expected *ex post* costs which include expected losses in producer and consumer surpluses from potential outbreaks as well as costs of response activities like medical expenses, recalls, etc. On the other hand, *ex ante* losses in producer and consumer surpluses in the case of less stringent regulation are relatively low. At relatively more stringent *ex ante* regulatory standard, with low levels of maximum allowable *E. coli* concentrations in irrigation water, *ex post* expected losses from potential outbreaks are relatively low as the probability of foodborne disease outbreak is reduced due to strict water quality control. However, more stringent *E. coli* regulations imply higher *ex ante* costs in terms of direct costs of prevention activities and losses in consumer and producer surpluses due to increased costs of production and prices.

Ex ante prevention efforts minimize the risks of foodborne disease outbreaks and/or enhance the capacity and the effectiveness of response activities. An increase (decrease) of *ex ante* investment in foodborne disease outbreak prevention decreases (increases) the *ex post* costs. Hence, an optimal strategy requires a balance of *ex ante* and *ex post* activities (Figure 1). Consistent with this rationale, we formulate a regulator's social benefit maximization problem where the regulator maximizes consumer and producer surplus values from consuming and producing product Y, minus the cost of water, expected social costs of water contamination related foodborne illnesses and cost of maintaining clean water. Let μ denote the quality of irrigation water, with low (high) values of μ corresponding to better (worse) quality water. The water quality distribution is denoted by $f(\mu)$ with μ belonging to the interval between (k and z) (Figure 2). The inverse demand is $P(Y(w), \theta)$, where θ is the water quality standard truncating the left tail of water quality distribution. $Y(w)$ is the production function and w is the quantity of irrigation water used in production of Y.

We write the problem of the regulator as

$$\underset{\theta,w}{\text{Max}}\, SW = \int_0^Y P(Y(w),\theta)dw - cw -$$
$$\left[\int_k^\theta S(\mu, Y(w);\alpha) f(\mu)d\mu - S(\theta, Y(w);\alpha)\int_z^\theta f(\mu)d\mu\right] - R(\theta;\beta) \tag{1}$$

where c is the cost of irrigation water, $S(\mu, Y(w);\alpha)$ is the damages from foodborne illnesses as a function of water quality, consumption, and consumer prevention efforts α. The term in the square brackets represents the expected damages from foodborne illnesses. If microbial water quality is above the regulatory standard, $\mu \geq \theta$, then damages are expressed in terms of θ because regulatory standard prevents water quality from falling above θ. On the other hand, if water quality does not exceed the regulatory standard, $\mu < \theta$, then the damages are expressed in terms of actual water quality μ (Figures 2a and 2b).

$R(\theta;\beta)$ is the cost of maintaining water quality standard with β as the cost shift parameter. We assume that $\frac{\partial s}{\partial \theta} > 0$, $\frac{\partial s}{\partial w} > 0$, $\frac{\partial^2 S}{\partial \theta^2} > 0$, and $\frac{\partial^2 S}{\partial w^2} > 0$. That is, an increase in the acceptable amount of pathogens in the irrigation water (less stringent regulation) and increase in the irrigation water use will increase social damages from contamination with an increasing rate. We also assume that $\frac{\partial R}{\partial \theta} < 0$ and $\frac{\partial^2 R}{\partial \theta^2} \geq 0$, i.e. cost of maintaining water quality standard is increasing with more stringent (lower θ) water quality standard with an increasing rate. The marginal costs of maintaining the microbial quality of irrigation is decreasing (i.e. $\frac{\partial^2 R}{\partial \beta \partial \theta} < 0$). We assume that a decrease in the stringency water quality standard decreases demand (i.e. $\frac{\partial P}{\partial \theta} \leq 0$) with a decreasing rate ($\frac{\partial^2 P}{\partial \theta^2} \leq 0$). Also, an increase in water use increases production of Y (i.e. $\frac{\partial Y}{\partial w} \geq 0$) with a decreasing rate ($\frac{\partial^2 Y}{\partial w^2} < 0$). We also assume that $\frac{\partial^2 S}{\partial Y \partial \theta} < 0$ which implies that marginal damage from additional consumption is decreasing. We assume that $\frac{\partial^2 S}{\partial \alpha \partial w} < 0$ which illustrates that an increase in consumers preventative efforts decreases marginal damages from additional water use and irrigation. We also assume that $\frac{\partial^2 S}{\partial w \partial \theta} > 0$, i.e. less stringent water quality standard leads to a rise in marginal damages from additional water use and irrigation.

$$\frac{\partial SW}{\partial \theta} = \int_0^Y \frac{\partial P}{\partial \theta} dY + \frac{\partial S}{\partial \theta} \int_z^\theta f(\mu) d\mu - \frac{\partial R}{\partial \theta} = 0 \tag{2}$$

$$\frac{\partial SW}{\partial w} = P[Y(w), \theta] \frac{dY}{dw} - c - \int_k^\theta \frac{\partial S}{\partial w} f(\mu) d\mu + \frac{\partial S}{\partial w} \int_z^\theta f(\mu) d\mu = 0 \tag{3}$$

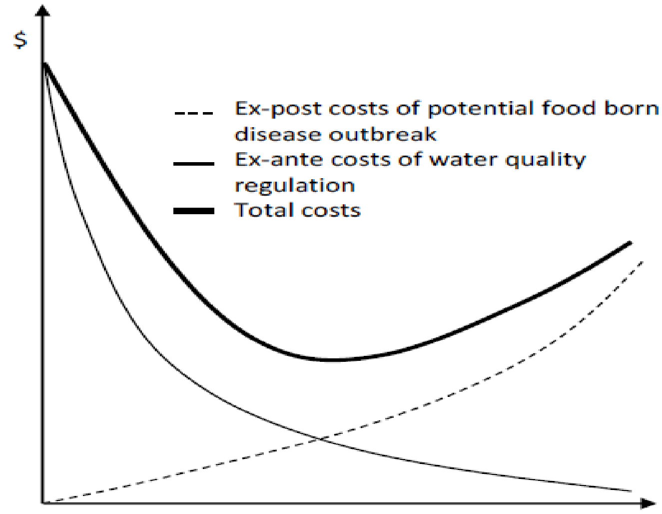
The first order conditions with respect to the water quality standard and irrigation (equations 2 and 3) lead to the following propositions (derivation in Appendix 1):

a) Increase in the cost of water increases irrigation water quality control efforts and decreases water use, i.e. $\frac{\partial \theta}{\partial c} \geq 0$ and $\frac{\partial w}{\partial c} \leq 0$;

b) Increase in the cost of implementing the irrigation water quality regulatory standard results in less stringent standard and lower water use, i.e. $\frac{\partial \theta}{\partial \beta} \geq 0$ and $\frac{\partial w}{\partial \beta} \leq 0$;

c) If consumers' prevention efforts and regulatory stringency are complementary ($S_{\theta\alpha}$>0), then increase in consumer led prevention efforts results in more stringent optimal water quality standard and lower water use, i.e. $\frac{\partial \theta}{\partial \alpha} \leq 0$ and $\frac{\partial w}{\partial \alpha} \geq 0$

d) If consumers' prevention efforts and regulatory stringency are substitutes ($S_{\theta\alpha}$<0), then increase in consumer led prevention efforts has an ambiguous effect on optimal water quality standard and optimal water use, i.e. $\frac{\partial \theta}{\partial \alpha}$ =? and $\frac{\partial w}{\partial \alpha}$ =?



Ex ante stringency of water quality standard

Figure 1: Cost minimization balance framework

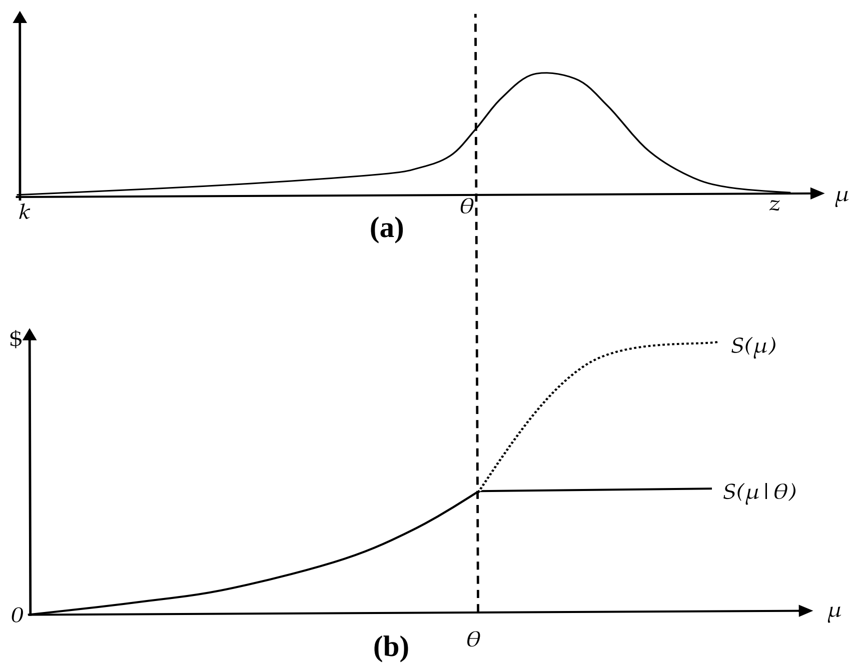


Figure 2a: Distribution of microbial water quality

Figure 3b: Damages from foodborne illnesses

3. Empirical Model

The empirical analysis relies on a two-stage stochastic price endogenous partial equilibrium model with random *E. coli* contamination in irrigation water. The model estimates a) *ex-ante* optimal water quality regulatory standard, planted acreage, and irrigation decisions; and b) *ex-post* harvest and storage delays in response to irrigation water contamination under mandatory testing of irrigation water according to the FSMA requirements. Two lettuce types are included in the model to allow for substitution in consumer demand.

County level planting, irrigation, and delay decisions are optimized with national supply constrained by aggregate county level production in the US plus net imports/exports. The objective function maximizes consumers' and producers' surplus minus aggregate costs of *E. coli*-related illness incidents and costs of implementing the regulatory standard. The constraints include demand and supply balance, stochastic water quality equations, yield and irrigation relationships, harvest and storage delay constraints reflecting STV and GM standards, and illness dose-response specifications. Irrigation water quality is specified as a spatial randomly distributed parameter while the regulatory standard for minimum water quality is endogenously estimated.

In this model states of nature depend on the stochastic water quality that varies spatially and across water sources. Assuming uniformly distributed states of nature, the model is formulated as follows:

$$W = \sum_n \frac{1}{N} \left(\sum_i \left[\int p_i^d\left(x_{n,i}^d\right) dx_{n,i}^d - \int p_i^s\left(x_{n,i}^s\right) dx_{n,i}^s \right] - \delta * ill_n \right) - \pi * \sum_{i,f,ct,ws,g} test_{i,f,ct,ws,g} - cw * \sum_{i,f,ct,ws,g} af_{i,f,ct,ws,g} - \sum_f \left[\left(M_{f,GM} - \xi_{f,GM} * \theta_{GM} \right) + \left(M_{f,STV} - \xi_{f,STV} * \theta_{STV} \right) \right] \quad (4)$$

where $p_i^d\left(x_{n,i}^d\right)$ and $p_i^s\left(x_{n,i}^s\right)$ represent inverse demand and supply functions, respectively. The demand functions reflect the product cross prices effects to allow for substitution. $x_{n,i}^d$ and $x_{n,i}^s$ are quantities of demand and supply of crop *i* under state of nature *n*. The first two expressions represent the sum of consumers' and producers' surplus measures. $test_{i,f,ct,ws,g}$ is 1 to represent testing irrigation water used for crop *i*, in farm type *f (*small, medium, and large), county *ct*, for water source *ws* (ground or surface), and for irrigation event g. Irrigation event refers to individual crop irrigation occasion. π is the cost per testing sample (in dollars), δ is average monetary loss value per each case of illness, ill_n is number of foodborne illnesses in each state of nature. *cw* is cost of irrigation water and $af_{i,f,ct,ws,g}$ is number of acres planted across categories. The last two terms in the objective function represent the cost of implementing the regulatory standard. $M_{f,GM}$ and $M_{f,STV}$ represent costs of the most stringent regulatory standard such that any amount of *E. coli* in irrigation water requires discarding the affected produce. $\xi_{f,GM}$ and $\xi_{f,STV}$ are marginal costs of implementing the microbial water quality regulatory standard, corresponding to GM and STV. θ_{GM} and θ_{STV} are GM and STV water quality standards, respectively. An increase in θ_{GM} and θ_{STV} (i.e. less strict water quality standard) reduces the costs of implementation. These costs are interpolated using cost estimates of Bovay et al. (2018). *N* is total number of states of nature and *W* is expected value of social welfare.

Following conventional partial equilibrium modeling methods, the supply and demand balance is represented is equation (5).

$$x_{n,i}^{d} - x_{n,i}^{s} \leq 0 \qquad \forall n, i \tag{5}$$

First stage choices in our model correspond to the planting and irrigation decisions made prior to crop exposure to contaminated irrigation water. Following previous literature, the historical and synthetic crop mix constraints are used to represent crop rotation at county level according to technological, managerial and agronomic limitations (Chen and Onal, 2012; Elbakidze et al., 2012; Schneider et al., 2007; Adams et al., 2003). Equations (6) and (7) represent these constraints using the observed historical county crop mix patterns from prior t years and a synthetic crop mix.[4]

[4] Synthetic crop mix is used to overcome the shortcomings of the historical crop mix that limits acreage to vary only within the historically observed bounds. The limitation of relying solely on historical crop mix is that this specification limits the flexibility of the model needed to adjust to the conditions not observed in historical data. The synthetic planted acreage enables greater flexibility in the model by extending the feasible decision space and is estimated following the methodology presented in Chen and Onal (2012). The estimated acreage elasticity and hypothetically low price of lettuce are used to obtain the synthetic county level acreages.

$$\sum_f af_{i,f,ct,ws} = \sum_t cmix_{i,ct,t} * \vartheta_{ct,t} + smix_{i,ct} * \tau_{ct} \qquad \forall i, ct, ws \tag{6}$$

$$\sum_t \vartheta_{ct,t} + \tau_{ct} = 1 \quad \forall ct \tag{7}$$

where $cmix_{c,ct,t}$ is the historical planted acreage of crop *i* (including two types of lettuce and aggregated other-vegetables) in year *t* in county *ct*; $\vartheta_{ct,t}$ and τ_{ct} are the choice variables between 0 and 1 that represent the percentage of acreage in county *ct* planted according to the proportions observed in year *t* or in the synthetic acreage estimate. $smix_{i,ct}$ is the synthetic crop acreage pattern. Constraint (7) forces a convex combination of historical and synthetic planted acreages. This constraint imposes crop rotation requirements for estimated crop acreage. We follow Chen and Onal, (2012) to generate synthetic crop mix that allows for greater flexibility in the model by extending the decision space.

In the second stage, crop harvest and storage delay decisions are made according to the FSMA proposed regulatory standard. First and second stage acreage decisions are linked in equation (8), where *as* denotes second stage acreage decisions that reflect delays in harvest and storage, while *af* denotes first stage planting and irrigation decisions.

$$\sum_d as_{n,i,f,ct,ws,g,d} = af_{i,f,ct,ws,g} \quad \forall n, i, f, ct, ws, g \tag{8}$$

Supply of crop *i* under state of nature *n* is constrained by the sum of production, yield ($y_{i,ct,g,d}$) times acreage ($as_{n,i,f,ct,ws,g,d}$) across counties, irrigation intensity (g), and delay in harvest and storage (d) according to equation (9) where $netex_i$ represents net export for crop *i*.

$$x^s_{n,i} = \sum_{f,ct,ws,g,d} as_{n,i,f,ct,ws,g,d} * y_{i,ct,g,d} - netex_i \quad \forall n, i \tag{9}$$

Following the guidelines of the FSMA, equation (10) compares the Geometric Mean and Statistical Threshold Value criteria to impose the delay of up to four days between the last irrigation and end of storage based on daily 0.5 log reduction of microbial water contamination.

$$\sum_d as_{n,i,f,ct,ws,g,d} = \begin{cases} as_{n,i,f,ct,ws,g,d0} \; if \begin{cases} GM_{n,i,f,ct,ws} * 10^0 \le \theta_{GM} \le max \\ and \\ STV_{n,i,f,ct,ws} * 10^0 \le \theta_{STV} \le max \end{cases} \\ as_{n,i,f,ct,ws,g,d1} \; if \begin{cases} GM_{n,i,f,ct,ws} * 10^{(-0.5)} \le \theta_{GM} \le GM_{n,i,f,ct,ws} * 10^0 \\ and \\ STV_{n,i,f,ct,ws} * 10^{(-0.5)} \le \theta_{STV} \le STV_{n,i,f,ct,ws} * 10^0 \end{cases} \\ as_{n,i,f,ct,ws,g,d2} \; if \begin{cases} GM_{n,i,f,ct,ws} * 10^{(-1.0)} \le \theta_{GM} \le GM_{n,i,f,ct,ws} * 10^{(-0.5)} \\ and \\ STV_{n,i,f,ct,ws} * 10^{(-1.0)} \le \theta_{STV} \le STV_{n,i,f,ct,ws} * 10^{(-0.5)} \end{cases} \\ as_{n,i,f,ct,ws,g,d3} \; if \begin{cases} GM_{n,i,f,ct,ws} * 10^{(-1.5)} \le \theta_{GM} \le GM_{n,i,f,ct,ws} * 10^{(-1.0)} \\ and \\ STV_{n,i,f,ct,ws} * 10^{(-1.5)} \le \theta_{STV} \le STV_{n,i,f,ct,ws} * 10^{(-1.0)} \end{cases} \\ as_{n,i,f,ct,ws,g,d4} \; if \begin{cases} \theta_{GM} \le GM_{n,i,f,ct,ws} * 10^{(-1.5)} \\ and \\ \theta_{STV} \le STV_{n,i,f,ct,ws} * 10^{(-1.5)} \end{cases} \end{cases}$$

$$\forall n, i, f, ct, ws, g \qquad (10)$$

The specification in (10) follows the FSMA regulatory standard, which requires a) θ_{STV} of 410 or less colony forming units (CFU) and b) θ_{GM} of 126 or less CFU per 100 ml of water. If either of these criteria are violated, then the irrigators have to either stop using water from the contaminated sources (unless treated), or extend the storage period and/or delay harvest to allow for microbial die-off (FDA, 2014). The producers can extend the pre-sale period for up to four days. Produce that is not in compliance even after four additional days of microbial die-off, based on the 0.5 log rate reduction of CFUs per day, is to be discarded. Equations (11) and (12) are used to obtain the GM and STV values for produce from across counties and farm types in each state of nature consistent with Bihn et al. (2017).

$$GM_{n,i,f,ct,ws} = 10^{(\sum_{t'} \log(CP_{n,i,f,ct,ws,t'}) + \sum_{g' \le g} test_{i,f,ct,ws,g,g'} * \log(C_{n,i,f,ct,ws,g'}))/n} \qquad \forall n, i, f, ct, ws \qquad (11)$$

$$STV_{n,i,f,ct,ws} = 10^{(GM_{n,i,f,ct,ws} + 1.282 * STD_{n,i,f,ct,ws})} \qquad \forall n, i, f, ct, ws \qquad (12)$$

where $C_{n,i,f,ct,ws,g}$ is concertation of *Generic E. coli* in water measured in terms of CFU/100 ml in state of nature *n* and $CP_{n,i,ct,f,ws,t'}$ is the concentration of *Generic E. coli* in the months prior to the last month of growing season (t').[5] $STD_{n,i,f,ct,ws}$ is the standard deviation of $\log\left(C_{n,i,f,ct,ws,g'}\right)$ and $\log\left(CP_{n,i,ct,f,ws,t'}\right)$. g' refers to the irrigation events prior to the current irrigation. *Generic E. coli* content of irrigation water source ($C_{n,i,f,ct,ws,g}$) is stochastic and generated according to equation (13).

$$C_{n,i,f,ct,ws,g} = Max(0, \Omega(k_1, k_2)) \qquad \forall n, i, f, ct, ws, g \tag{13}$$

where Ω is either Lognormal or Weibull distribution function and (*k1*, *k2*) are either mean and variance or the scale and shape parameters, respectively.[6,7] Only specific types of *E. coli*, including *E. coli O157:H7* cause foodborne outbreaks (CDC, 2020). Therefore, based on the availability of the data pertaining to the prevalence of *O157:H7* relative to *Generic E. coli*, we focus on the *E. coli O157:H7* as the strain that causes foodborne illnesses in the model. *R* is the ratio of *E. coli O157:H7* to *Generic E. coli* (Pang et al., 2017; Ottoson et al., 2011; Muniesa et al., 2006). It is assumed that *E. coli O157:H7* in irrigation water transmits to the irrigated crops according to equation (14) where CFUs from each irrigation *g* are aggregated reflecting die-off from delays in harvesting and storage. The volume of water consumed by the crop after irrigation is determined by irrigation efficiency (*iref*) (evapotranspiration divided by applied water per acre). Hence, the amount of *E. coli* present in the crop after irrigation is proportional to the consumptive use (Solomon et al., 2002). It is assumed that the crop is irrigated by Furrow irrigation technology as

[5] In this model we focus on irrigations that take place in the last month and assume that crops are irrigated every 6 days (Smith et al., 2011).

[6] Density plots, Q-Q- plots that provide the empirical quantiles versus the analytical quantiles, and P-P plots that show empirical functions versus fitted distribution functions along with Akaike Information Criteria (AIC) and Schwarz's Bayesian information criteria (BIC) are used to select the best fitted distribution function per county. However, the *E. coli* concentration level in ground water is only available for three counties. We obtain Weibull distribution functions for these three counties according to the NWIS and STORET Databases. To drive the distribution function of *Generic E. coli* concentration in ground water in other counties, we shifted the distribution function *of Generic E. coli* concentration in surface water in each county to the left by a shift parameter, based on this assumption that ground water is safer than surface water. The shift parameter is the averaged mean of the distribution functions of ground water quality in the counties that data was available for them.

[7] The data available at: www.waterqualitydata.us should provide more details.

most common in California and Arizona (FDA, 2016). d represents days of delay in harvesting and storage.

$$CN_{n,i,f,ct,d,ws,g} = \sum_{g' \leq g} \left(\frac{C_{n,i,f,ct,ws,g}}{100}\right) * (iref) * R * 0.96 * e^{-\frac{tg(g')^{\zeta}}{\epsilon}} * 10^{-0.5*d} * \eta \qquad \forall n, i, f, ct, d, ws, g \tag{14}$$

$C_{n,i,f,ct,ws,g}$ is divided by 100 to convert the unit of *Generic E. coli* concentration from CFU/100 ml to CFU/ml. In the baseline scenario, it is assumed that 50 percent of *Generic E. coli* in water source remains in the applied irrigation water at the time of application ($\eta = 0.5$).[8] The die-off function ($e^{-\frac{tg(g')^{\zeta}}{\epsilon}}$) is assumed to have an exponential form (Brouwer et al., 2017). This function is used to allow for decay of *E. coli* between each irrigation event and the last event. The concentration of *E. coli* that transfers to the crop at each irrigating event is reduced by ($e^{-\frac{tg(g')^{\zeta}}{\epsilon}}$) until the last event, where $tg(g')$ represents the time period between each irrigation event , $g,'$ and subsequent irrigation events.

The FSMA regulation requires that farmers develop a microbial water quality profile (MWQP) which determines the required delay in harvesting and storage according to criteria in expressions (10, 11, and 12). The initial MWQP is based on at least 20 water samples for the untreated surface water and at least 4 samples for the ground water. The MWQP must be updated every year. Consistent with the FSMA, we assume that to create MWQP farmers have obtained 15 samples of surface water and 3 samples of the ground water in the previous months with the remaining 5 and 1 sample obtained in the last month of each growing season (FDA, 2020). We assume that there are 5 irrigation events in the last month and total 15 irrigation events growing season.

We adopt a dose-response approach developed by Pang et al. (2017) and consistent with the framework proposed by Lichtenberg (2010). Serving size ($SERV_i$) and pathogen concentration per gram of produce after delay in harvest and storage are used to estimate pathogen content ($D_{n,i,f,ct,ws,g,d}$) per contaminated serving (equation 15). A dose-response relation (16) estimates the probability ($p_{n,i,f,ct,ws,g,d}$) of illness per contaminated serving, where ρ and ω denote dose-

[8] In the sensitivity analysis we examine the influence of this parameter.

response parameters (Pang et al., 2017). Probability of illness per contaminated serving is used to estimate the number of expected illnesses per state of nature (16). Since yield is calculated in hundred weights, it is multiplied by 50,802.3 (grams/CWT) in equation (17) to obtain the number of illnesses per state of nature. In equation (16) α represents consumers effort. α is used to examine the impact of consumers effort on optimal water quality standard.[9]

$$D_{n,i,f,ct,ws,g,d} = \sum_{ws,th} CN_{n,i,f,ct,d,g,ws} * SERV_i \qquad \forall n,i,f,ct,ws,g,d \qquad (15)$$

$$p_{n,i,f,ct,ws,g,d} = \left[1 - \left(1 + \frac{D_{n,i,f,ct,ws,g,d}}{\omega}\right)^{-\rho}\right] * \left(\frac{1}{\alpha}\right) \qquad \forall n,i,f,ct,ws,g,d \qquad (16)$$

$$ill_n = \sum_{i,f,ct,ws,g,d} p_{n,i,f,ct,ws,g,d} * as_{n,i,f,ct,ws,g,d} * \ y_{i,ct,g,d} * \frac{50{,}802.3}{SERV_i} \qquad \forall n \qquad (17)$$

4. Data

Our empirical analysis focuses on the microbial irrigation water quality in lettuce industry as prescribed by the FDA standard. Lettuce is of particular interest in terms of food safety because all lettuce is consumed fresh without further processing. Several recent foodborne diseases outbreaks have also been traced to contaminated lettuce (see footnote 1). We focus on California and Arizona as the major lettuce producing regions in the US.

Data on production, consumption, planted acreage, price, import, export, and applied irrigation water for lettuce production are obtained from U.S. Department of Agriculture, Economic Research Service (USDA)/Economic Research Service (ERS), and USDA/National Agricultural Statistics Service (NASS). Data are collected from 43 counties in Arizona and California. Farms are categorized into three types: small, medium, and large.[10] The model includes two types of lettuce: "Head" and "Leaf and Romaine". In 2017, approximately 18,194 acres of

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[9] The formulation in equation (16) implies substitution between consumers' prevention efforts and regulatory stringency ($S_{\theta\alpha}$<0). The model can be solved with an alternative formulation $p_{n,i,f,ct,ws,g,d} = \left[1 - \left(1 + \frac{D_{n,i,f,ct,ws,g,d}}{\alpha*\omega}\right)^{-\rho}\right]$, to represent complementary ($S_{\theta\alpha}$>0). Since this scenario is unlikely in our context, we focus on the substitution case in the empirical model.

[10] Small farms are considered to be farms with less than 50 acres, medium farms are assumed to be farms with acres between 50 and 500, and large farms are farms with more than 500 acres consistent with USDA (2017).

lettuce were planted in California, and 48,964 acres in Arizona. California and Arizona produced nearly all of the U.S. “Head” and “Romaine and Leaf” lettuce in 2017 (USDA, 2018).

Demand and supply functions are formulated using own-price elasticity of demand, cross-price elasticities of demand, and own-price elasticity of supply (Table 1). Elasticity estimates are obtained from prior literature.

Table 1: Own and cross elasticities of demand and own-price elasticity of supply of “Head” and “Leaf and Romaine” lettuce

Elasticity	Lettuce Type	“Head"	“Leaf and Romaine”
Elasticity of demand	“Head”	-0.84	0.035
	“Leaf and Romaine”	0.015	-0.84
Elasticity of supply	“Head”	0.56	-
	“Leaf and Romaine”	-	0.56

Note:

Own-price elasticity of demand is obtained from Okrent and Alston (2012); Own-price elasticity of supply is obtained from Lohr and Park (1992); Cross-price elasticities of demand are obtained from Ferrier et al. (2016). We use the average of the cross-price elasticities between “Head” and “Leaf” and “Head” and “Romaine” as the proxy for the cross-price elasticity between “Head” lettuce and the combined “Leaf and Romaine” lettuce. We apply a similar assumption for the cross-price elasticity of “Leaf and Romaine” lettuce with respect to “Head” lettuce.

Past spatial microbial water quality data are obtained from the National Water Quality Monitoring Council (USGS-EPA, 2020). The data contains historical and current water data from over 1.5 million sites in different states and locations. This database includes water quality data from the USGS National Water Information System (NWIS), the EPA STOrage and RETrieval (STORET), and the USDA ARS Sustaining the Earth’s Watersheds-Agricultural Research Database System (STEWARDS). Water quality data, including *Generic E. coli* concentrations, are available for various ground and surface water sources. Number of observations for *Generic E. coli* concentration varies across counties from 32 in San Joaquin county to 5,931 in Ventura county. These data are used to form county specific Lognormal and Weibull probability density functions for *Generic E. coli* concentrations in irrigation water. The parametrized county specific probability density functions are used in five hundred random draws in each model solution. Mean values of CFU/100 ml of water quality distributions across counties are provided in Appendix 2. An explanation of the variables and parameters and their units is provided in Tables A1 and A2 in Appendix 3.

5. Results

For validation and calibration purposes, the empirical model is used to reproduce prices and quantities observed under baseline conditions with no *E. coli* contamination. Model solutions reproduce lettuce prices and quantities that are comparable to the observed data (See appendix Table A3). Quantities, prices, and corresponding supply and demand function parameter specifications from 2016 for "Leaf and Romaine" lettuce, and 2008 for "Head" lettuce, the years with the largest observed outputs respectively, are used for the base case to allow for greatest flexibility in solutions in terms of supply. The solutions of the base case are within 2% of observed quantities and within 3% of prices observed in the respective years.

To examine the cost effectiveness of the water quality regulatory standard as proposed by FDA, we compare the values of social welfare obtained under the FSMA standard and the corresponding value with no regulation of water quality and no management of contaminated produce. Under the no regulation scenario, sufficiently high values of θ_{GM} and θ_{STV} (680 CFU/100 ml for GM and 2,214 CFU/100 ml for STV) are chosen so that constraint 10 produces no delay in harvesting and storage and the costs of implementing the regulatory standard ($\sum_f\left[\left(M_{f,GM} - \xi_{f,GM} * \theta_{GM}\right) + \left(M_{f,STV} - \xi_{f,STV} * \theta_{STV}\right)\right]$) are zero. The results in Table (2) show that with \$4,000 per case as the cost of foodborne illness the FSMA regulatory standard is not cost effective. However, if the cost of illness increases to \$10,000 per case, the results show that the FSMA is cost effective unless implementation costs exceed \$2 million.

Table 2: Regulatory standard, welfare, and price of two types of lettuce

Scenario	Regulatory Standard (CFU/100 ml)		Social Welfare[a] (\$)		Price of Lettuce (\$)	
	GM	STV	Cost of Illness=\$4,000	Cost of Illness=\$10,000	"Head"	"Leaf and Romaine"
FSMA	126	410	2.385B	2.343B	23.4	16.6
Optimal Base Case Scenario	214.2	697	2.388B	2.344B	22.9	16.4
No FSMA	680	2,214	2.387B	2.341B	22.7	16.2

[a] The reported values exclude costs of regulatory standard implementation.

Results also show that the optimal water quality standard is less stringent than the proposed standards in the FSMA. While the FDA's analysis of the regulatory standard did not explicitly factor in surplus losses for consumers and producers, our model account for these costs. As a result, we obtain a less stringent regulatory standard. Table (2) also shows that expected prices of "Head" and "Leaf and Romaine" lettuce increase by 0.98% and 1.38%, respectively in the optimal base case scenario relative to the solutions with no FSMA regulatory standard and more *E. coli* outbreak. This result is similar to the results of Bovay and Sumner (2017) who show that wholesale tomato prices would increase by 2.4% due to the FSMA.

As shown in proposition (a), costlier irrigation water can decrease irrigation and reduce the optimal stringency of microbial water quality regulatory standard. We examine this effect empirically by varying cost of irrigation water across five scenarios in Table (3). In the base scenario, cost of irrigation water per irrigation event per acre is zero. Costs increase in the subsequent scenarios from $3.8 per irrigation event per acre for small and medium farms and $6.0 for large farms (USDA, 2013) to $114 and $180, respectively. As expected, the results show that as cost of irrigation water increases water use decreases and optimal water quality standard stringency decreases. These results are consistent with the expectations because increase in cost of irrigation water and consequent decrease in water use reduces the amount of *E. coli* transferred to crops and results in fewer cases of foodborne illness. With fewer foodborne illnesses, stringency of optimal water quality standard decreases.

Table 3: Impact of increase in cost of irrigation water on optimal water quality standard and water use

Scenario	Lettuce Type	Cost of irrigation water ($/acre-irrigation)		Water Use[a]	GM Standard (CFU/100 ml)	STV Standard (CFU/100 ml)
		Small and Medium Farm	Large Farm			
Base Scenario	"Head" "Leaf and Romaine"	0	0	622,447 628,420	214.2	697
Scenario 1	"Head" "Leaf and Romaine"	3.8	6	622,447 628, 420	214.2	697
Scenario 2	"Head" "Leaf and Romaine"	38	60	622,447 622,266	214.2	697
Scenario 3	"Head" "Leaf and Romaine"	76	120	620,095 617,519	252	820
Scenario 4	"Head" "Leaf and Romaine"	114	180	614,654 616,883	287	933

[a] Irrigation water use is measured in terms of irrigation events times irrigated acreage.

As discussed in the theory section, if consumers' illness prevention efforts and regulatory stringency are substitutes, then increase in consumer's efforts has an ambiguous impact on the optimal water quality standard and optimal irrigation water use. Such substitute behavior may arise when consumers receive information about the stringency of water quality standard. For example, when consumers are informed that the water quality standard is strict enough to minimize contamination due to irrigation, they may exert lower effort to wash fresh vegetables. In such a circumstance, the consumer's effort and regulatory stringency can be used as substitutes to reduce food contamination related illnesses. This case is similar to Roe (2004) showing that when consumers' and firms' effort are substitutes, additional firms' effort leads to less consumers' effort. For instance, if consumers are informed that the industry is taking some actions to decrease the level of pathogens in food, then consumers might believe that their efforts have less impact and may decrease their efforts.

Table 4: Impact of increase in consumers' effort on optimal water quality standard and water use

Scenario	Lettuce Type	Water Use[a]	GM Standard (CFU/100 ml)	STV Standard (CFU/100 ml)
Base Scenario	"Head"	622,447	214.2	697
	"Leaf and Romaine"	628,420		
Scenario 1	"Head"	642,605	264.6	861
	"Leaf and Romaine"	634,387		
Percentage Change (%)	"Head"	3.2	23.5	23.5
	"Leaf and Romaine"	0.9		

[a] Irrigation water use is measured in terms of irrigation events times irrigated acreage.

In the empirical analysis we assume that an increase in consumers effort reduces the probability of foodborne illness. The results (Table 4) indicate that an increase in the consumer's effort by a factor of ten reduces stringency of optimal water quality standard and increases water use for irrigating "Head" and "Leaf and Romaine" lettuce by 3.2% and 0.9%, respectively. These results are consistent with expectations based on the assumption that when consumers exert more effort to prevent foodborne outbreaks, the probability of illness and the number of foodborne illnesses decrease. As a result, production increases and stringency of water quality standard decreases. Note that the empirical formulation is a special case of the theoretical model. Given the assumptions in the damage formulation and the relationship between damages, consumers' prevention effort, irrigation water use, and water quality standard, we obtain a clear result for the impact of consumers' effort on optimal water quality standard and irrigation water use.

To examine the relationship between stringency of regulation and costs of implementation we vary the costs of implementation according to the scenarios outlined in Table 5. Consistent with the theoretical analysis, the empirical results (Table 5) show that an increase in the cost of implementing the regulatory standard reduces the optimal stringency of the standards. Less stringent standard reduces delay in harvest and storage and increases foodborne illnesses. As a result, optimal production decreases so that marginal costs of additional illnesses are balanced against marginal benefits of additional lettuce supply in terms of consumer and producer surplus.

Table 5: Impact of increase of cost of implementation of the FSMA on optimal water quality standard and water use

Scenario	Lettuce Type	Marginal cost of implementation of the FSMA-GM ($)			Marginal cost of implementation of the FSMA-STV ($)			Water Use[a]	GM Standard (CFU/100 ml)	STV Standard (CFU/100 ml)
		Small Farm	Medium Farm	Large Farm	Small Farm	Medium Farm	Large Farm			
Base Scenario	"Head" "Leaf and Romaine"	1.3	8.9	12.3	0.06	0.25	0.35	622,447 628,420	214.2	697
Scenario 1	"Head" "Leaf and Romaine"	2.6	17.8	24.6	0.12	0.5	0.7	621,575 628,311	364.1	1,184.9
Scenario 2	"Head" "Leaf and Romaine"	3.9	26.7	36.9	0.18	0.75	1.05	621,575 624,949	407.0	1,324.3

[a] Irrigation water use is measured in terms of irrigation events times irrigated acreage.

5.1. Sensitivity Analysis

We examine the sensitivity of the results to variation in the key parameters by varying one parameter value at a time while keeping other parameter values at their base value. The range of values for monetary value of foodborne illness damages (δ), persistence of *Generic E. coli* found in source water and delivered via irrigation (η), and number of days between irrigation events (tg) in the sensitivity analysis are provided in Table (6). Scenario 3 is the base case. Table (7) presents the results of sensitivity analysis in terms of the ratio of the optimal standard stringency and the stringency of the standard as proposed by FDA (GM=126 and STV=410). The key finding from the sensitivity analysis is that the FDA water quality standards are not optimal over a wide range of parameter values. An increase in the cost of foodborne illnesses and the proportion of *E. coli* in water source that remains in the applied irrigation water increase stringency of the optimal water quality standard. These results are consistent with the expectations. An increase in the cost of foodborne illnesses and greater transmission of *E. coli* increase marginal benefits of water quality standard stringency. Increase in time between irrigation events decreases optimal standard stringency because of greater die-off of *E. coli*. After last irrigation, the cumulative *E. coli* concentration in the crop is lower when number of days between irrigation events is higher, which decreases foodborne illnesses.

Table 6: Values of parameters for sensitivity analysis

Scenarios	δ	η	tg
1	1500	0.3	4
2	3,000	0.4	5
3 (base)	4,000	0.5	6
4	5,000	0.6	7
5	6,500	0.7	8

Table 7: Results of the sensitivity analysis in terms of the ratio of optimal water quality standard and the FSMA standard

Scenarios	δ	η	tg
1	2.4	2.0	1.5
2	2.4	2.0	1.5
3 (base)	1.7	1.7	1.7
4	1.5	1.5	2.0
5	0.9	1.5	2.0

6. Conclusions and Policy Implications

This study examines the economic efficiency of the FDA guidelines in response to the FSMA pertaining to irrigation water quality focusing on the proposed standards for microbial quality of irrigation water and the required delays in harvest and storage when microbial quality standards are exceeded. We first provide a theoretical analysis of the optimality of water quality assurance efforts. The FDA proposed regulatory standard is examined empirically using the lettuce market as a case study. To our knowledge this paper is the first attempt to examine the food safety-related irrigation water quality regulatory standard as proposed by FDA using an economic framework that includes a detailed exposure and dose-response formulations. The empirical analysis uses a stochastic two stage price endogenous partial equilibrium model with recourse. *E. coli* contamination of irrigation water is treated as a spatially explicit stochastic parameter based on the Lognormal or Weibull probability density functions obtained using historical water quality data.

We find that the expected prices of "Head" and "Leaf and Romaine" lettuce increase by 0.98% and 1.38%, respectively relative to the solutions with no FDA regulation and more foodborne illness cases. This result is consistent with Bovay and Sumner (2017) who show that the price of tomatoes increases by 2.4% due to implementation of the FSMA. We also find that after considering the regulatory standard's impact on consumers' and producer' surplus, the FDA proposed water quality standards are not optimal and should be less stringent. We also observe that optimal water quality standard may depend on the scarcity of water. When water is scarce, reduced irrigation and production can lead to less stringent standard being more preferred then the more stringent standard. Also, the results show that if the monetary value of damages per foodborne illness is on average $4,000 per case, then the regulatory standard as proposed in the FSMA is not cost effective. If the cost per illness case increases to $10,000, then the FDA regulatory standard is cost effective unless implementation costs exceed $2 million.

These results are important from policy point of view because tradeoffs between food safety and food prices are often difficult to assess and represent a significant reason for the challenging nature of food policy debates. We observe that the balance of investment in *ex ante* regulatory stringency versus *ex post* costs of illness incidents requires a detailed examination of economic factors linked with exposure and dose-response formulations. Using such a model, and the assumed values for key parameters, we observe that for the case of lettuce the FSMA guidelines for irrigation water quality as proposed in 2014 are excessively stringent. This study points to the importance of considering producers and consumers surplus implications for determining the stringency of food safety related regulatory standards. Lower stringency of standards reduces the costs borne by the producers and decrease prices relative to higher stringency standards. However, lower stringency results in greater number of illnesses and associated costs. The design of the food safety regulation, including microbial irrigation water quality standard, requires balance of marginal damages from illnesses and marginal consumer and producer welfare values. This conclusion is in line with other studies that have highlighted the importance of consumer and producer welfare values in food safety-related regulations. For example, Wilson and Anton (2006) provide optimal set of the Application of Sanitary and Phytosanitary (SPS) Measures taking into account the net welfare effects. They find that considering consumers' and producers' surplus and total welfare into the analysis, there are a set of measures that increase national welfare relative to the measures suggested in the guidelines (measures such as vaccinations, culling animals, tariffs or bans).

We close by explaining some of the limitations of this study. As proposed by FDA, *Generic E. coli* is used as indicator microorganism in the water. However, only specific types of *E. coli*, including *E. coli* O157:H7, cause foodborne outbreaks. *E. coli* O157:H7 is the most prevalent kind of *E. coli* in North America (FDA, 2012) which causes severe illness. Therefore, our analysis is based on the prevalence of *E. coli* O157:H7 as the strain that causes foodborne illnesses. There are other types of pathogens that can cause foodborne illnesses. FDA has identified six other types of *E. coli* that cause foodborne illnesses including: *E. coli* O26, O45, O103, O111, O121, and O145 (Bertoldi, et al. 2018). Inclusion of other pathogens can improve cost effectiveness of the regulatory standard.

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Appendix 1

Proposition 1 is derived from the following equations. From the first order conditions in equations (2) and (3) we can derive the hessian matrixes as

$$|H_{11}| = \frac{\partial^2 SW}{\partial \theta^2} = \int_0^Y \frac{\partial^2 P}{\partial \theta^2} dY + \frac{\partial^2 S}{\partial \theta^2} \int_z^\theta f(\mu)\, d\mu + \frac{\partial S}{\partial \theta} f(\theta) - \frac{\partial^2 R}{\partial \theta^2} \leq 0 \tag{A1}$$

$$|H_{22}| = \frac{\partial^2 SW}{\partial w^2} = \frac{\partial P}{\partial Y}\left(\frac{dY}{dw}\right)^2 + P\frac{d^2 Y}{dw^2} - \int_k^\theta \frac{\partial^2 S}{\partial w^2} f(\mu)\, d\mu + \frac{\partial^2 S}{\partial w^2} \int_z^\theta f(\mu) d\mu \leq 0 \tag{A2}$$

$$|H_{12}| = \frac{\partial}{\partial w}\left(\frac{\partial SW}{\partial \theta}\right) = \frac{\partial}{\partial w}\left(\frac{\partial S}{\partial \theta}\right) \int_z^\theta f(\mu)\, d\mu + \frac{dY}{dw}\frac{\partial P}{\partial \theta} \leq 0 \tag{A3}$$

$$|H_{21}| = \frac{\partial}{\partial \theta}\left(\frac{\partial SW}{\partial w}\right) = \frac{\partial}{\partial \theta}\left(\frac{\partial S}{\partial w}\right) \int_z^\theta f(\mu)\, d\mu + \frac{dP}{d\theta}\frac{dY}{dw} \leq 0 \tag{A4}$$

Then we use the hessian matrixes to derive the impact of the parameters of interest on the optimal water quality standard and optimal irrigation water use.

(1) The effect of water cost (c)

$$\begin{bmatrix} H_{11} & H_{12} \\ H_{21} & H_{22} \end{bmatrix} \begin{bmatrix} \frac{\partial \theta}{\partial c} \\ \frac{\partial w}{\partial c} \end{bmatrix} = \begin{bmatrix} -\frac{\partial}{\partial c}\left(\frac{\partial SW}{\partial \theta}\right) \\ -\frac{\partial}{\partial c}\left(\frac{\partial SW}{\partial w}\right) \end{bmatrix} = \begin{bmatrix} 0 \\ 1 \end{bmatrix} \tag{A5}$$

$$\frac{\partial \theta}{\partial c} = \frac{\begin{vmatrix} 0 & H_{12} \\ 1 & H_{22} \end{vmatrix}}{H_{11}H_{22} - H_{12}H_{21}} = \frac{-H_{12}}{H_{11}H_{22} - H_{12}H_{21}} \geq 0 \tag{A6}$$

$$\frac{\partial w}{\partial c} = \frac{\begin{vmatrix} H_{11} & 0 \\ H_{21} & 1 \end{vmatrix}}{H_{11}H_{22} - H_{12}H_{21}} = \frac{H_{11}}{H_{11}H_{22} - H_{12}H_{21}} \leq 0 \tag{A7}$$

(2) The effect of cost of implementation of the FSMA (β)

$$\begin{bmatrix} H_{11} & H_{12} \\ H_{21} & H_{22} \end{bmatrix} \begin{bmatrix} \frac{\partial \theta}{\partial \beta} \\ \frac{\partial w}{\partial \beta} \end{bmatrix} = \begin{bmatrix} -\frac{\partial}{\partial \beta}\left(\frac{\partial SW}{\partial \theta}\right) \\ -\frac{\partial}{\partial \beta}\left(\frac{\partial SW}{\partial w}\right) \end{bmatrix} = \begin{bmatrix} \frac{\partial}{\partial \beta}\left(\frac{\partial R}{\partial \theta}\right) \\ 0 \end{bmatrix} \tag{A8}$$

$$\frac{\partial\theta}{\partial\beta} = \frac{\begin{vmatrix}\frac{\partial}{\partial\beta}\left(\frac{\partial R}{\partial\theta}\right) & H_{12}\\ 0 & H_{22}\end{vmatrix}}{H_{11}H_{22}-H_{12}H_{21}} = \frac{\frac{\partial}{\partial\beta}\left(\frac{\partial R}{\partial\theta}\right)H_{22}}{H_{11}H_{22}-H_{12}H_{21}} \geq 0 \qquad \text{(A9)}$$

$$\frac{\partial w}{\partial\beta} = \frac{\begin{vmatrix}H_{11} & \frac{\partial}{\partial\beta}\left(\frac{\partial R}{\partial\theta}\right)\\ H_{21} & 0\end{vmatrix}}{H_{11}H_{22}-H_{12}H_{21}} = \frac{-\frac{\partial}{\partial\beta}\left(\frac{\partial R}{\partial\theta}\right)H_{21}}{H_{11}H_{22}-H_{12}H_{21}} \leq 0 \qquad \text{(A10)}$$

(3) *The effect of consumer's efforts* (α)

$$\begin{bmatrix}H_{11} & H_{12}\\ H_{21} & H_{22}\end{bmatrix}\begin{bmatrix}\frac{\partial\theta}{\partial\alpha}\\ \frac{\partial W}{\partial\alpha}\end{bmatrix} = \begin{bmatrix}-\frac{\partial}{\partial\alpha}\left(\frac{\partial SW}{\partial\theta}\right)\\ -\frac{\partial}{\partial\alpha}\left(\frac{\partial SW}{\partial w}\right)\end{bmatrix} = \begin{bmatrix}\frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial\theta}\right)\int_\theta^z f(\mu)d\mu\\ \int_k^\theta \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)f(\mu)d\mu + \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)\int_\theta^z f(\mu)d\mu\end{bmatrix} \qquad \text{(A11)}$$

$$\frac{\partial\theta}{\partial\alpha} = \frac{\begin{vmatrix}\frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial\theta}\right)\int_\theta^z f(\mu)d\mu & H_{12}\\ \int_k^\theta \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)f(\mu)d\mu + \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)\int_\theta^z f(\mu)d\mu & H_{22}\end{vmatrix}}{H_{11}H_{22}-H_{12}H_{21}} =$$

$$\frac{H_{22}\frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial\theta}\right)\int_\theta^z f(\mu)d\mu - H_{12}\left[\int_k^\theta \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)f(\mu)d\mu + \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)\int_\theta^z f(\mu)d\mu\right]}{H_{11}H_{22}-H_{12}H_{21}} \qquad \text{(A12)}$$

Depending on the sign of $S_{\alpha\theta}$, the first term on the right-hand side in the numerator can be negative or positive while the second term is positive. This indicates that whether the impact of consumer's effort on optimal water quality standard is positive or negative depends on the sign of $S_{\alpha\theta}$.

$$\frac{\partial\theta}{\partial\alpha}\begin{cases} =? & , if \ \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial\theta}\right) < 0\\ \leq 0 & , if \ \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial\theta}\right) > 0\end{cases} \qquad \text{(A13)}$$

$$\frac{\partial w}{\partial\alpha} = \frac{\begin{vmatrix}H_{11} & \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial\theta}\right)\int_\theta^z f(\mu)d\mu\\ H_{21} & \int_k^\theta \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)f(\mu)d\mu + \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)\int_\theta^z f(\mu)d\mu\end{vmatrix}}{H_{11}H_{22}-H_{12}H_{21}} =$$

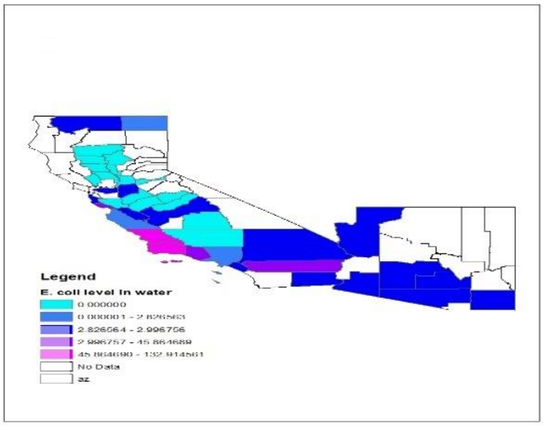
$$\frac{\left[\int_k^\theta \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)f(\mu)d\mu + \frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial w}\right)\int_\theta^z f(\mu)d\mu\right]H_{11} - H_{21}\frac{\partial}{\partial\alpha}\left(\frac{\partial S}{\partial\theta}\right)\int_\theta^z f(\mu)d\mu}{H_{11}H_{22}-H_{12}H_{21}} \qquad \text{(A14)}$$

Similarly, the first term on the right-hand side in the numerator is positive, while the second term can be positive or negative (depending on the sign of $S_{\alpha\theta}$). This indicates that the sign of $S_{\alpha\theta}$ determines whether the impact of consumer's effort on optimal water use is positive or negative.

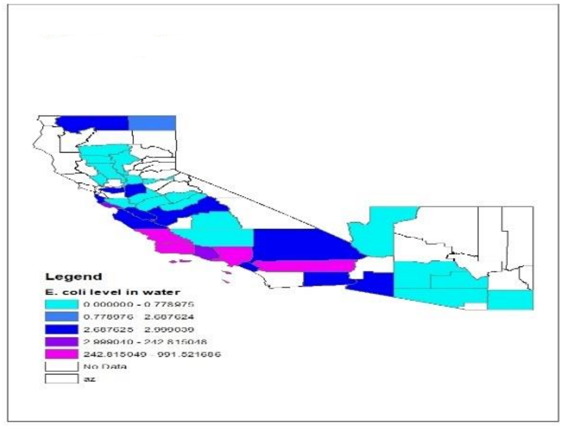
$$\frac{\partial w}{\partial \alpha}\begin{cases} =? & , if \ \frac{\partial}{\partial \alpha}\left(\frac{\partial S}{\partial \theta}\right) < 0 \\ \geq 0 & , if \ \frac{\partial}{\partial \alpha}\left(\frac{\partial S}{\partial \theta}\right) > 0 \end{cases} \tag{A15}$$

Appendix 2

Figure A1: Average Generic E. coli concentration per 100 ml for surface and ground water in Arizona and California generated by 500 random draws.



a) Surface water



b) Ground water

Appendix 3

Table A1: Summary of variables used in the empirical model

Symbol	Variable	Unit
W	Expected value of social welfare	$
$p_i^d(x_{n,i}^d)$	Inverse demand function	-
$p_i^s(x_{n,i}^s)$	Inverse supply function	-
$x_{n,i}^d$	Quantity demanded of crop *i*	CWT
$x_{n,i}^s$	Quantity supplied of crop *i*	CWT
ill_n	Number of illness cases	
$af_{i,f,ct,ws,g}$	*Ex ante* planted acreage	Acres
$as_{n,i,f,ct,ws,g,d}$	*Ex post* planted acreage	Acres
$cmix_{i,ct,t}$	Historical percentage of planted acreage of crop *i*	Acres
$\vartheta_{ct,t}$	Convex hull choice variable	-
$smix_{i,ct,m}$	The synthetic crop acreage pattern	Acres
$\tau_{ct,m}$	Convex hull choice variable	-
$y_{i,ct,g,d}$	Yield of crop *i*	CWT
$del_{i,f,ct,ws}$	Delay in harvesting after last irrigation	Days
$CN_{i,f,ct,ws,th,n}$	Concentration of *E. coli* in crop after delay in harvesting	CFU/ml
$D_{i,f,ct.n}$	Dose per contaminated serving	CFU/serving
$p_{i,f,ct,n}$	Probability of illness per serving	Probability/ serving

Table A2: Summary of parameters used in the empirical model

Symbol	Parameter	Baseline Values	Unit	Source
$test_{i,f,ct,ws,g}$	Water quality testing	-	-	-
R	Ratio of *E. coli O157:H7* to *Generic E. coli*	$10^{-1.9}$	-	Pang et al. (2017); Ottoson et al. (2011)
$C_{n,i,f,ct,ws,g}$	Concertation of *Generic E. coli* in water	-	CFU/100 ml	USGS and EPA (2020)
$CP_{n,i,ct,f,ws,t\prime}$	Concertation of *Generic E. coli* in water in the previous months	-	CFU/100 ml	USGS and EPA (2020)
$GM_{n,i,f,ct,ws}$	Geometric mean	-	CFU/100 ml	Model estimation
$STV_{n,i,f,ct,ws}$	Statistical Threshold Value	-	CFU/100 ml	Model estimation
θ	Water quality standard	GM:126; STV:410	CFU/100 ml	FDA (2016) FDA (2016)
$SERV_i$	Serving size of crop *i*	85	Gram	FDA (2015)
ω	Dose-response function parameter	229.3	-	Pang et al. (2017)
ρ	Dose-response function parameter	0.267	-	Pang et al. (2017)
$tg(g)$	Number of days between irrigation events	6	Days	Smith et al. (2011)
ζ	Die-off function parameter	2.1	-	Brouwer et al. (2017)
ϵ	Die-off function parameter	0.59	-	Brouwer et al. (2017)
π	Cost per testing sample	87.3	$	FDA (2015)
δ	Economic losses per illness	4,000	$	USDA (2019)
η	Proportion of *E. coli* in water source that remains in the applied irrigation water	0.5	-	Authors assumption
$iref$	Irrigation efficiency	0.7	-	USDA (2013)
α	Consumers effort	1	-	Authors assumption
cw	Cost of irrigation water	Small farm: 3.8; Medium farm: 3.8; Large farm: 6.0	$/Acre/irrigation	USDA (2013)
$\xi_{f,GM}$	Marginal cost of implementation of the FSMA based on GM	Small farm: 1.3; Medium farm: 8.9; Large farm: 12.3	$	Authors calculations based on Bovay et al. (2018)
$\xi_{f,STV}$	Marginal cost of implementation of the FSMA based on STV	Small farm: 0.06; Medium farm: 0.25; Large farm:0.35	$	Authors calculations based on Bovay et al. (2018)
$M_{f,GM}$	Costs such that any amount of *E. coli* requires discarding the irrigated produce based on GM	Small farm: 3076.8; Medium farm: 11,696; Large farm: 16,174	$	Authors calculations based on Bovay et al. (2018)
$M_{f,STV}$	Costs such that any amount of *E. coli* requires discarding the irrigated produce based on STV	Small farm: 2,807; Medium farm: 10,671; Large farm: 14,756	$	Authors calculations based on Bovay et al. (2018)

Table A3: Comparison of simulations for all historical years and the base case with the observed data for "Head" and "Leaf and Romaine" lettuce

a) Observed Data

	Lettuce Type	Year										Base Case	
		2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2008	2016
Quantity (1,000 CWT)	"Leaf and Romaine"	31,720	30,731	37,203	36,599	37,481	36,139	34,405	35,352	40,962	40,838	-	40,962
	"Head" Lettuce	51,357	49,517	49,331	49,275	50,106	44,588	46,160	43,526	45,914	42,905	51,357	-
Price ($/CWT)	"Leaf and Romaine"	25.24	31.33	28.26	31.42	25.15	13.63	13.88	22.95	14.74	17.21	-	14.74
	"Head"	20.25	22.4	20.85	22.29	16.83	24.97	22.45	26.51	24.5	32.17	20.25	-

b) Model Solution

	Lettuce Type	Year										Base Case	
		2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2008	2016
Quantity (1,000 CWT)	"Leaf and Romaine"	31,720	30,811	37,203	36,598	37,481	36,139	34,405	35,352	40,962	40,838	-	40,365
	"Head"	50,899	49,081	48,310	49,028	49,862	44,437	45,932	43,381	45,148	42,905	51,257	-
Price ($/CWT)	"Leaf and Romaine"	25.48	31.5	28.45	31.65	25.24	13.65	13.93	23.08	14.74	17.26	-	15.1
	"Head"	19.96	22.08	21.15	22.03	16.64	24.75	22.31	26.28	24.84	32.19	20.56	-

c) Percentage Change

	Lettuce Type	Year										Base Case	
		2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2008	2016
Quantity (%)	"Leaf and Romaine"	0	0.26	0	0	0	0	0	0	0	0	-	-1.46
	"Head"	-0.89	-0.88	-2.07	-0.5	-0.49	-0.34	-0.49	-0.33	-1.67	0	-0.19	-
Price (%)	"Leaf and Romaine"	0.95	0.54	0.67	0.73	0.36	0.15	0.36	0.57	0	0.3	-	2.44
	"Head"	-1.43	-1.43	1.44	-1.17	-1.13	-0.88	-0.62	-0.87	1.39	0.06	1.53	-