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How Effective Are Federal Food Safety Regulations?

The Case of Eggs and Salmonella *Enteritidis*

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RESOURCES FOR THE FUTURE

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Abstract

In 2009 the Food and Drug Administration (FDA) estimated that its shell egg rule would reduce illness from *Salmonella* Enteritidis (*S*E) by about 79,000 cases annually (37%), with a range from about 30,000 to 191,000 cases avoided. I assess the effectiveness of this rule, which requires farmers who sell eggs to adopt *S*E control measures, by comparing illness from *S*E with illness from other *Salmonella* serotypes, using a differences-in-differences approach. The data reject the hypothesis that the rule reduced illnesses by FDA's best 2009 estimate, but do not reject a hypothesis of no effect. The percentage of young broilers that test positive for *S*E has a modest effect on the incidence of human cases of salmonellosis caused by *S*E. Recent literature offers two other reasons to adjust FDA's prospective 2009 calculations. One adjustment would follow the Centers for Disease Control's use of a lower multiplier to infer the total number of (unobserved) cases of illness from those confirmed by positive lab tests. A second adjustment would lower the average cost of *Salmonella* cases, by recognizing lower risk of severe sequelae. These adjustments and the new retrospective assessment of the effectiveness of the rule together suggest that the benefits of FDA's egg rule may be a small fraction of the prospective estimate of benefits, and less than the prospective estimate of costs. I conclude with some policy recommendations to make food safety regulations more effective.

Key Words: food safety, salmonella, retrospective, effects of regulation

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How Effective Are Federal Food Safety Regulations? The Case of Eggs and *Salmonella* Enteritidis

Randall Lutter*

1. Introduction

The 2011 Food Safety Modernization Act (FSMA)[(1)] has led the Food and Drug Administration (FDA) to issue nine separate economically significant regulations, of which eight have been proposed but not yet issued in final form.[(2)] FDA is issuing these regulations with very limited information about their cost-effectiveness. In particular, FDA has developed eight of these nine rules without providing any quantitative information about the reduction in human illness that might be expected from promulgation and enforcement of these rules (see Appendix). In addition, FDA is developing these regulations without any new analysis of the effects of existing food safety regulations. Yet several of these, such as rules mandating hazard analysis of critical control points for juice[(3)] and for seafood,[(4)] and FDA's egg rule,[(5)] are conceptual precursors of the regulations that FDA is developing under the FSMA. An assessment of the effects of extant regulations thus seems germane for current food safety policy decisions.

Retrospective assessments of the effects of federal regulations are a hallmark of two executive orders signed by President Obama (EO 13563 and EO 13610) and features of earlier executive orders going back to President Reagan (EO 12291). Indeed, Section 1(a) of President Obama's EO 13563 states that the regulatory system "must measure, and seek to improve, the actual results of regulatory requirements." Conducting such analysis is typically challenging, however, because of data deficiencies and inadequate quasiexperiments appropriate for drawing causal inferences.[(6,7,8)] In addition, federal regulatory agencies assigned responsibility for retrospective studies by these EOs have little incentive to spend scarce resources on retrospective as opposed to prospective analyses.[(9,8)]

The literature on food safety includes numerous studies using FoodNet, the active surveillance system of the Centers for Disease Control and Prevention (CDC), which is widely thought to be the best source of data on human illnesses from foodborne pathogens.[(10,11)] CDC researchers routinely use FoodNet data to report changes in incidence by pathogen,[(12)] but these

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reports provide very little quantitative information about the effectiveness (or ineffectiveness) of different regulatory actions. The CDC also reports aggregate estimates of the public health burden of foodborne illnesses,[10] but without providing either prospective or retrospective quantitative estimates of the reductions in burden attributable to specific rules.

FDA has provided quantitative prospective estimates of the costs, and sometimes of the benefits, of its regulations, but I am unaware of a retrospective analysis that it has completed of the benefits or costs of extant food safety regulations. A minor exception is an FDA statement about an earlier FDA rule addressing refrigeration and labeling of eggs.[5] FDA noted that after that earlier rule took effect in 2001, the estimated number of illnesses from *Salmonella* Enteritidis in the United States decreased by nearly 9 percent in 2002.[1] FDA did not test the statistical significance of the estimated decline, which is likely subject to confounding anyway.

All of these analyses of foodborne illnesses have to overcome a variety of technical difficulties. Underreporting is generally high, with only a small proportion of illnesses reported to public health authorities or confirmed by laboratory testing.[10] Only a small fraction of illnesses are ever linked to specific pathogens, such as a particular bacterium, virus, or protozoan. Illness linked to a specific pathogen may not have resulted from contaminated food, because transmission can also occur through other means, such as contact with animals or contaminated drinking water. It may also result from consumption of contaminated food during travel to other countries. The multiplicity of pathogens and sources means that linking reductions in disease to regulatory efforts is difficult—the noise drowns out the signal.

This paper seeks to improve understanding of the effectiveness of federal efforts to promote food safety by evaluating retrospectively the effectiveness of controls on a single relatively important pathogen, *Salmonella* Enteritidis (*S*E). *Salmonella* causes more illness than any other pathogen routinely tracked by the CDC, and recent estimates of *Salmonella* incidence exceed the Healthy People 2020 Goal level of 11.4 cases per 100,000.[12] Among the different serotypes of *Salmonella*, *S*E is implicated in more cases of illness than any other. Human exposure is through food, primarily chicken, which is regulated by the US Department of Agriculture (USDA) through its Food Safety and Inspection Service (FSIS), and eggs, which are regulated by FDA if they are sold in their shells. FDA issued a major rule in 2009 addressing the

[1] Following FDA, I italicize *Salmonella* and capitalize both *Salmonella* and Enteritidis, except when quoting other sources that use different conventions.

safety of so-called "shell eggs" and estimated that it would lead to significant reductions in incidence of human illness from *S*E.[(5)]

I use CDC's FoodNet database on human cases of foodborne illness to compare the incidence of illness from *S*E and other pathogens, including other serotypes of *Salmonella*, before and after implementation of FDA's egg rule. Other serotypes of *Salmonella* are an appropriate control for *S*E because they occur commonly in poultry and are influenced by the same risk factors. A key distinction is that *S*E, unlike all other *Salmonella*—that is, *Salmonella* Non-Enteritidis (*S*NE)—is introduced into the interior of the egg in ovum.[(13)] In addition, FDA reported that for outbreaks where a vehicle of transmission of *S*E was identified, 81 percent of outbreaks and 79 percent of illnesses identified through such outbreaks were attributed to eggs.[(5)] Thus infection controls in egg farms are likely to affect predominantly, and perhaps exclusively, the incidence of disease from *S*E but not from *S*NE.

Using a differences-in-differences approach, I reject the hypothesis that the rule reduced illness by the amount estimated prospectively by FDA in 2009, but I am unable to reject a hypothesis that the rule had no effect on the incidence of *S*E. I am able to show a modest effect of the percentage of young broilers that test positive for *S*E on the incidence of human cases of salmonellosis caused by *S*E.

I also review the food safety literature since FDA issued its egg rule in 2009 and find two reasons to update or adjust FDA's ex ante calculations in a manner that would result in substantially lower overall benefits. One such adjustment would follow CDC's use of a lower multiplier to infer the total number of (unobserved) cases of illness from those confirmed by positive lab tests. A second adjustment would lower the average cost of *Salmonella* cases, by recognizing lower risk of severe sequelae. The net effects of both adjustments is a reduction by a factor of four.

These adjustments, when coupled with the new retrospective assessment of reductions in illness, suggest that FDA's prospective benefits estimate was too high by a factor of about 16, although the uncertainty means it could be too high by as little as a factor of 7.. Further, it suggests that net benefits may be positive or negative; FDA in 2009 estimated benefits outweighed costs by a factor of 17.

In the rest of the paper, I provide the history and background of recent federal efforts to promote food safety and a review of FDA's egg rule. Next, I present an analysis of the effect of the rule on human illness. I then provide a discussion of this analysis before concluding and offering some policy recommendations.

2. History and Background

FDA is developing new food safety regulations without having carefully assessed retrospectively the effects of existing food safety regulations. The FDA website lists more than two dozen retrospective reviews conducted under EO 13563, but just one of these addresses food safety—the modernization of current food Good Manufacturing Practice regulations through a rule mandated by FSMA requiring preventive controls.(14) FDA's retrospective review program thus appears to lack detailed retrospective analysis of the effectiveness or cost-effectiveness of preexisting regulations. The apparent lack of new retrospective analysis may not be surprising, given that FDA's limited resources appear fully occupied with drafting regulations to implement FSMA.

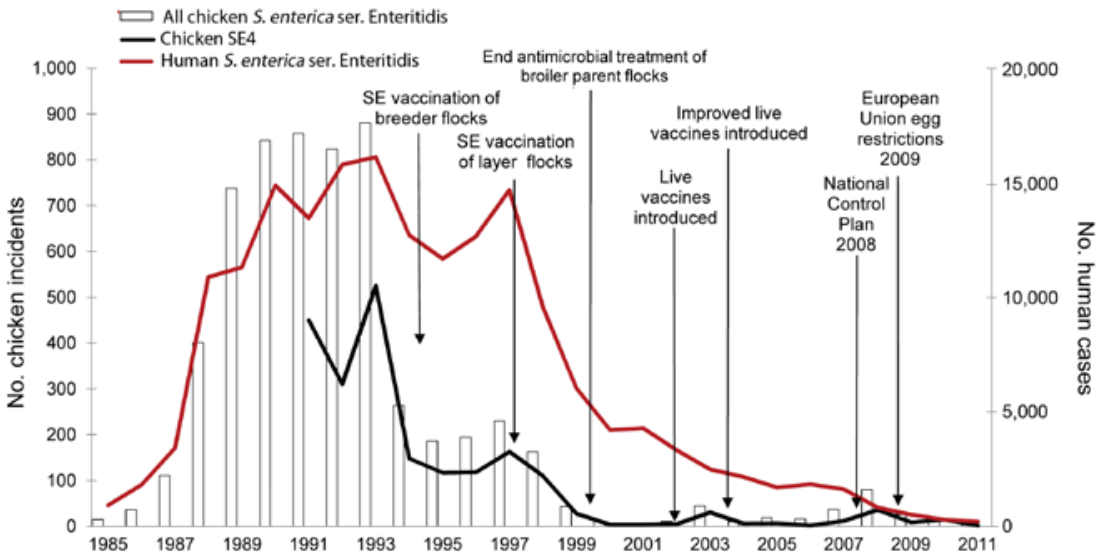
There is new attention to congressional funding of FDA's food safety program. Congress has not funded FDA's food safety program at a level consistent with earlier projections.(15) The Congressional Budget Office estimated that the costs of implementing the new FSMA would amount to $580 million between 2011 and 2015, but congressional appropriations have been a fraction of that amount.

The USDA's FSIS, which regulates the safety of meat and poultry products, lists retrospective evaluation of regulatory initiatives as a "priority." It also states, "Determining the impact of regulations may provide valuable guidance for potential adjustments and/or the development of future policy."(16) USDA's 2014 Retrospective Review Plan Report does not mention, however, any specific food safety rule by FSIS that is the subject of retrospective analysis.(17)

Retrospective analyses of the effects of interventions to promote food safety exist in other countries, although these are largely qualitative. Using data from the United Kingdom over several decades, Lane et al. link *S*E in chickens to human illness and to specific interventions.(18) The authors note that vaccination of chicken breeder flocks preceded a 70 percent decrease in reports of *S*E infections in chickens during 1994. Laboratory reports of human cases of *S*E plateaued from 1994 to 1998. A second stage of the decline of the epidemic followed the introduction and later extension of the vaccination program to layer flocks, enhanced farm hygiene, and management standards implemented for major egg-layer flocks. Laboratory-confirmed reports of human cases of *S*E fell roughly fourfold—by nearly 15,000 annually—between the height of the epidemic and the recent years 2008 to 2011, as shown in the following figure. While the analysis of Lane et al. did not use econometric or statistical methods typically deemed necessary to infer causal relationships, it did provide suggestive evidence of public

health gains associated with different interventions. Reductions in total cases of illness likely far exceeded the reductions in laboratory-confirmed cases. This history is instructive because early growth in the number of *S*E cases was also observed in the United States. In its 2009 rule, FDA stated, "The rate of *S*E isolates reported to CDC increased from 0.6 per 100,000 population in 1976 to 3.6 per 100,000 population in 1996."[(5)]

Figure 1. A Retrospective Appraisal of *Salmonella* in the United Kingdom[(18)]



As an example of a retrospective assessment of trends in foodborne illness in the United States, the USDA's Economic Research Service in 2002 linked trends toward safer preparation of hamburgers with small but meaningful reductions in risk of foodborne illness. Specifically, it said, "The change in behavior reported in the 1996 Hamburger Preparation Quiz (HPQ), a national survey of hamburger cooking and ordering preferences, translates to an estimated 4.6-percent lower risk of E. coli O157:H7 infection and an estimated $7.4-million annual reduction in medical costs and productivity losses."[(19)] This analysis, however, offered merely suggestive links from the change in food safety education to behavior. Moreover, it did not link changes in disease incidence to a federal rule.

The CDC regularly reports trends in incidence of human illness linked to foodborne pathogens. It usually does so without ascribing specific, quantifiable changes in incidence to particular regulatory programs. For example, CDC has recently acknowledged that cases of illness from *S*E have not been falling as originally forecast.[(12)] It reported:

> Enteritidis, the most commonly isolated serotype [of *Salmonella*], is often associated with eggs and poultry. The incidence of Enteritidis infection was lower in 2013 compared with 2010-2012, but not compared with 2006-2008. This might be partly explained by the large Enteritidis outbreak linked to eggs in 2010. Ongoing efforts to reduce contamination of eggs include FDA's Egg Safety Rule, which requires shell egg producers to implement controls to prevent contamination of eggs on the farm and during storage and transportation. FDA required compliance by all egg producers with ≥50,000 laying hens by 2010 and by producers with ≥3,000 hens by 2012.[(12)]

Enteritidis is the most frequently reported serotype of *Salmonella* among those isolated in specimens sent to laboratories for analysis. For 2013, Crim et al. report, "Among 6,520 (90%) serotyped *Salmonella* isolates, the top serotypes were Enteritidis, 1,237 (19%); Typhimurium, 917 (14%); and Newport, 674 (10%)."[(12)] *Salmonella* Enteritidis is the most frequently identified serotype of human health significance among young chickens and ground chicken.[(20)] Other serotypes commonly found in young broiler products include Kentucky, Typhimurium, and Heidelberg.[(21)]

3. FDA'S Egg Rule

A retrospective appraisal of the effects of FDA's egg rule should build on an understanding of the rule and the supporting analysis. In this section, I summarize the egg rule briefly, review FDA's supporting analysis, and evaluate whether FDA's 2009 estimates of the baseline risk and costs of illness from *S*E are consistent with current methods.

3.1. FDA's Egg Rule

The analysis that FDA conducted to support its 2009 egg rule projected large net benefits, more than $1.3 billion annually, as shown in Table I.[(5)] FDA estimated that "eventual" benefits, which would accrue starting with the fifth year after the rule took effect, exceeded estimated costs by more than a factor of 17. FDA estimated that the expected value of total costs would be $82 million annually (90 percent CI: $58-$117 million).[(5)] In its analysis, all the quantified benefits were reductions in risk of illness from *S*E. Although FDA's egg rule acknowledged that *Campylobacter* and *Salmonella* other than Enteritidis had been found on the exterior of chicken eggs, illness from the presence of pathogens on the exterior of the eggshells seems likely to be rare, and FDA did not expect benefits from reductions in pathogens other than *S*E to be large. About 85 percent of this reduction in *S*E risk came from two key provisions: rodent and pest control and refrigeration. Diversion, a requirement that contaminated eggs be treated so as to

achieve a 5 log reduction prior to sale, generates another 14 percent of the projected reduction in illness.

Table I. Summary of FDA's Estimates of Benefits and Costs for the Egg Rule[5]

	Annual Costs (millions)		Annual Illnesses Averted		Total Benefits (millions)		Net Benefits (millions)	
Provision	Initial	Eventual	Initial	Eventual	Initial	Eventual	Initial	Eventual
On-Farm Measures								
Rodent and Pest Control	$21.4	$21.4						
Biosecurity	$5.3	$5.3						
Cleaning and Disinfecting	$0.3	$0.3	19,477	38,866	$349	$696	$327	$674
Refrigeration	$20.2	$20.2	33,682	28,888	$603	$517	$583	$497
Environmental Testing	$4.6	$4.6						
Egg Testing	$9.7	$7.0						
Diversion	$12.5	$9.0	15,312	11,096	$274	$199	$262	$190
Procurement of *SE*-Monitored Chicks and Pullets	$2.1	$2.1	320	320	$6	$6	$4	$4
On-Farm Administrative Measures								
Plan Design	$1.2	$1.2						
Record Keeping	$10.2	$9.8						
Training	$0.3	$0.3						
Registration	$0.0	$0.0						
Total	$87.7	$81.2	68,791	79,170	$1,231	$1,417	$1,144	$1,336

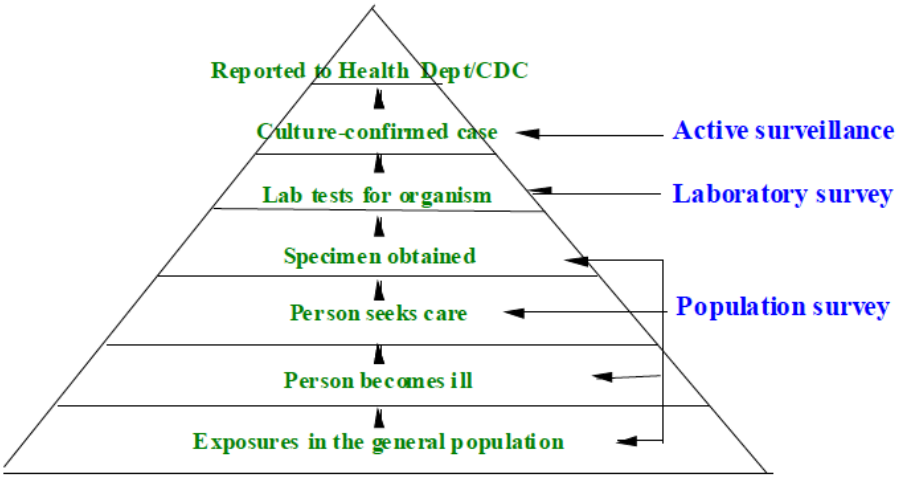
In 2009, FDA projected that its egg rule would result in relatively large reductions in human cases of *SE*. Using a quantitative analysis of uncertainty for the "eventual" scenario, FDA estimated that the total annual human cases of *SE* would fall by 79,170, with a 90 percent confidence interval extending from 29,863 to 191,273.[5] A reduction of 79,170 would represent about 37 percent of the baseline number of 215,000 *SE* cases that FDA estimated would occur annually from sources of exposure in the United States. Thus FDA's egg rule would be expected to reduce *SE* incidence by about 37 percent. A reduction of 68,791—that is, the "initial" reduction—would amount to a drop of about 32 percent. FDA did not report any confidence intervals associated with the initial benefits scenario. A confidence interval for the "initial" reduction with the same percentage reductions as for the "eventual" estimates would extend from

12 percent to 77 percent of *S*E incidence. If the ratio of total unobservable illnesses to reported and confirmed illnesses was constant, then FDA's estimates would imply a lower-bound effectiveness estimate of a 12 percent reduction in the FoodNet confirmed cases.

Annual incidence of lab-confirmed *S*E cases reported to CDC's active surveillance system, FoodNet, was 2.3 per 100,000 from 2000 through 2009. The standard deviation of annual incidence of *S*E in FoodNet during this period was 0.36 cases per 100,000, or 16 percent of the annual incidence.

It is important to distinguish between two different concepts of incidence, as shown by the CDC's burden of illness pyramid. One relies on culture-confirmed cases. A much larger figure reflects all illnesses, including those without laboratory confirmation of the presence of a pathogen, a specimen collected, or even an effort to seek medical attention. FDA has in the past used a factor of 38 to estimate the total cases of salmonellosis from the number of *Salmonella* illnesses estimated through a surveillance program.[(5)] In 2013, the CDC's Salmonella Atlas used 29 total cases of illness for every lab-confirmed reported case.[(22)]

Figure 2. Burden of Illness Pyramid[(23)]



3.2. Baseline Risks: Observed vs Total Cases of Salmonella Enteritidis

New information about differences between observed and total human cases of *Salmonella* may have changed how one should perceive the reliability of FDA's 2009 prospective estimates of total avoided human cases.

FDA's prospective estimate of the baseline number of egg-related illnesses from *S*E in 2006 was 141,990,[(5)] a figure that appears to be based on information that may no longer be consistent with best practices. FDA derived this estimate by making three adjustments to the number of cases estimated through "passive surveillance": underreporting (a factor of 38); exposure outside the United States (a 16 percent reduction); and causes unrelated to eggs (a 34 percent reduction). FDA's estimate of total egg-related *S*E cases in the United States in 2006 was 141,990. This figure for total cases in 2006 equals 6,740 × 38 × (1 – .16) × (1 – .34), where 6,740 is the agency's estimate of 2006 SE cases based on passive surveillance.[(5)] FDA developed these estimates based on earlier work by Voetsch et al.[(24)]

Voetsch et al. developed the multiplier for underreporting using the results of a telephone-based population survey with four-week recall of acute episodes of diarrhea for the sites covered by FoodNet. Voetsch et al. compared the results of this survey, which had a response rate of 50 percent, with the cases of confirmed nontyphoidal *Salmonella* infections reported by laboratories participating in FoodNet.[2] They argued that the estimate of culture-confirmed cases derived by age-adjusting and extrapolating to the United States (36,242), is similar to the estimate from passive reporting (32,926), suggesting that the national passive surveillance for nontyphoidal *Salmonella* is "relatively complete."[(24)]

FDA also developed lower- and upper-bound estimates of the total (baseline) number of cases of egg-related illness caused by *S*E by using different multipliers for the underreporting and causes unrelated to eggs. FDA used a range of 23 to 61 percent for underreporting, and a range of 53 to 79 percent for the percentage of SE cases that come from eggs. The agency did not develop estimates of the likelihood of values outside this range. Thus it is unclear what likelihood can be assigned to estimates within these bounds.

More recently, Scallan et al. applied a probabilistic approach to develop new estimates, including a lower multiplier of 29.3 for underreporting, with a 90 percent confidence interval of 21.8 to 38.5. Their purpose was different from that of the earlier FDA analysis, which sought to estimate the number of *Salmonella*-related illnesses nationally from consumption of FDA-regulated eggs. Instead, Scallan et al. wanted to estimate the burden of disease from nontyphoidal *Salmonella* infection related to consumption of foods in the United States. Unlike

[2] Nontyphoidal serovars of *Salmonella* present as gastrointestinal disease. Typhoid fever is caused by *Salmonella* serovars adapted to humans or higher primates.

FDA's analysis for its rule, which focused on 2006 data, Scallan et al. used data from 2005 to 2008.[10] Their methods nonetheless provide an opportunity to review this part of the original FDA analysis.

In general, Scallan et al. estimate the number of domestically acquired foodborne illnesses due to each known pathogen using five inputs. For *Salmonella*, however, they adopt a more sophisticated procedure, distinguishing between severe (bloody) and mild (nonbloody) diarrhea. Scallan et al. also estimated FoodNet cases of *Salmonella* acquired outside the United States to be 11 percent, with lower and upper bounds of 7 percent and 15 percent.[25] Table II summarizes estimates from Scallan et al. that are useful and relevant for a retrospective appraisal of this part of FDA's 2009 analysis.

As shown in Table II, there are two discrepancies between FDA's 2009 prospective estimates of the baseline number of illness averted and current estimates. FDA's analysis of the egg rule uses a multiplier of 38 for underreporting, while the later work of Scallan et al. uses a lower multiplier of 29.3, though it ascribes this to underdiagnosis (as opposed to underreporting). FDA's RIA also uses an estimate of 16 percent for the number of confirmed cases that result from exposure to foreign travel, while Scallan et al. instead provide an estimate of 11 percent with an upper bound of 15 percent. The net effect of these two discrepancies, which have qualitatively offsetting effects, suggests that FDA's prospective estimate of the total number of human cases of illness attributable to *S*E in the baseline should be revised downward by 18 percent to reflect Scallan et al.: specifically, 116,000 /141,990 = 81.7 percent.[10,25]

Table II. Calculating Baseline Total Cases of Illness

FDA's Shell Egg Final Rule *Salmonella* Enteritidis (Table 1[5])		CDC: Nontyphoidal *Salmonella* (Scallan et al., Table 2[10])		Updated Estimate of Total Baseline Human Cases Linked to *SE*
NA		41,930	FoodNet active surveillance lab-confirmed cases of illness from nontyphoidal *Salmonella* (adjusted to national population)	
Number of lab-confirmed cases of *Salmonella* enteritidis reported in 2006, through passive reporting	6,740	NA		6,740
Underreporting adjustment factor	38	1	Underreporting	
Underdiagnosis adjustment factor (and range)	1	29.3 (21.8-38.5)	Underdiagnosis	29.3
Exposure from foreign travel (percentage and range)	0.16	0.11 (0.07-0.15)	Travel-related	0.11
Causes unrelated to eggs	0.34	NA		0.34
Nonfoodborne	NA	0.06	Nonfoodborne	
Implied total number of *SE* cases from US consumption of shell eggs.	141,990	NA		116,000
Annual number of domestically acquired cases of illness from foodborne *SE*	215,140	1,027,800	Annual number of domestically acquired foodborne cases of illness from foodborne nontyphoidal *Salmonella*	175,600

3.3. Economic Costs of a Case of SE

Estimates of the economic costs of a case of *S*E have changed since FDA issued its final rule. At that time FDA estimated that the value of total quality adjusted life-days, including the value of mortality risk, and the associated medical costs would be approximately $17,900 per case.[(5)] While FDA did not present uncertainty bounds associated with this estimate, it did conduct a sensitivity analysis, which showed a range of values from $7,600 to $49,500 per case, reflecting different discount rates and unit values for mortality risk reduction.

More recently, Minor et al. estimated the per-case costs of a wide range of foodborne illnesses, using methods selected to reflect welfare more accurately than earlier methods.[(26)] For nontyphoidal *Salmonella*, these authors reported a mean estimate of $5,337, with a range from $4,868 to $5,915. While nontyphoidal *Salmonella* is a broader set of illnesses than *S*E, to the extent that they have comparable profiles for the risks of different outcomes, this more recent research suggests that the earlier estimate of benefits may have been too high by about a factor of three.

3.4. The Food Safety Inspection Service and SE on Poultry Products

Poultry products may carry different *Salmonella* serotypes, and human exposure to raw or badly cooked poultry thus creates a risk of illness. In response to a request for data under the Freedom of Information Act, the USDA's FSIS kindly provided monthly data on the percentage of broilers that tested positive for *S*E, by month, for the years 2006 through 2013. These data should not be interpreted as a random sample, however, because the sampling varies by size of plant and compliance status. These data had a mean of 1.24 percent with a standard deviation of 0.826 percent; for five months, FSIS reported no positive test results for *S*E.

FSIS has sought to establish a statistical link between the frequency of *Salmonella* occurrence by serotype with human salmonellosis cases by serotype.[(20)] The FSIS analysis, which uses a volume-weighted measure of annual incidence of *S*E, noted that the Spearman correlation of yearly percentages was statistically significant (for cases and broilers $p = 0.0049$, and for cases and ground chicken $p = 0.016$). The FSIS analysis does not estimate the effect of reducing occurrence of *S*E on regulated products on human illness, nor did it evaluate effectiveness of recent regulatory interventions.

In June 2006, FSIS began to schedule establishments based on new criteria that are risk-based.[(27)] The new scheduling criteria focused FSIS resources on establishments with the most *Salmonella*-positive samples, including serotypes most frequently associated with human

salmonellosis as defined by the CDC. As a result of this change in sampling, FSIS reports that results from establishments prior to 2006 cannot be compared with those taken from 2006 onward.

4. Data Analysis

I focus on confirmed cases of salmonellosis as reported in CDC's FoodNet database and evaluate cases of *S*E compared with cases of illness from other serotypes of *Salmonella.* The other pathogens chosen for comparison in this evaluation should be like *S*E in respects unrelated to *S*E's presence in eggs. Specifically, the other pathogens should occur on the same nonegg products where *S*E typically occurs, such as broilers and ground chicken. In addition, they should not occur commonly on nonegg products where *S*E is rare, such as beef. Finally, they should follow a seasonal pattern reasonably similar to that of human cases of illness from *S*E.

Since FoodNet tracks individual cases of illness, a key question is the preferred unit of observation. More than a third of cases lack information on the date of first onset of symptoms, so a measure of daily counts of illness seems inefficient. Given that the data cover only eight years, a focus on annual observations also seems inefficient. I choose to analyze monthly counts of illness, which are summarized in Table III. I exclude cases of illness where the patient acknowledged having traveled internationally prior to falling ill.

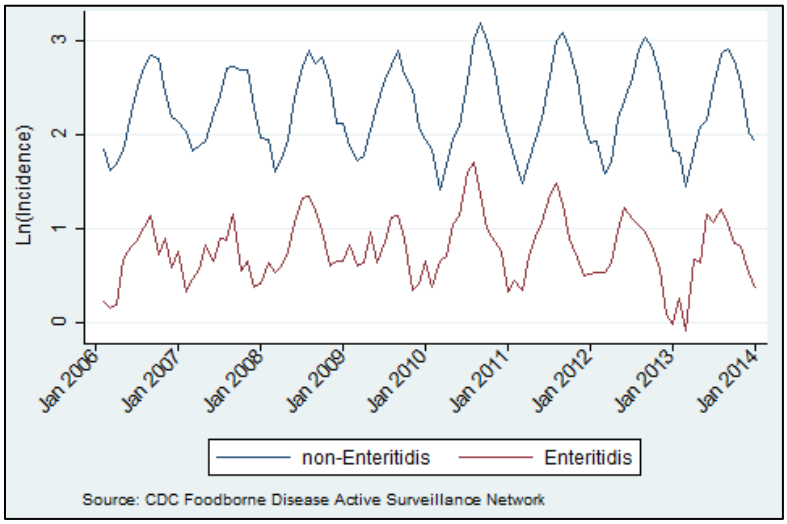
Table III. Total Monthly Counts of Illness from *Salmonella*[(28)]

Variable definition	Obs.	Mean	Std. Dev.	Min.	Max.
Monthly count of illness from *Salmonella* other than Enteritidis	96	506.3	233.3	192	1,135
Monthly count of illness from *Salmonella* Enteritidis	96	107.7	39.9	44	261

In its analysis of FoodNet data, CDC has used negative binomial regressions to estimate incidence. It notes that the reported incidence may change with the addition of new geographic areas to FoodNet, because of the variability of incidence across areas. Since 2006, however, the geographic scope of FoodNet has been relatively constant. Population has increased only from 45.3 million to 48.3 million from 2006 to 2013. For population, I use linear interpolations of the annual population figures reported by CDC in its FoodNet reports. I estimate negative binomial regressions and also explore alternative models.

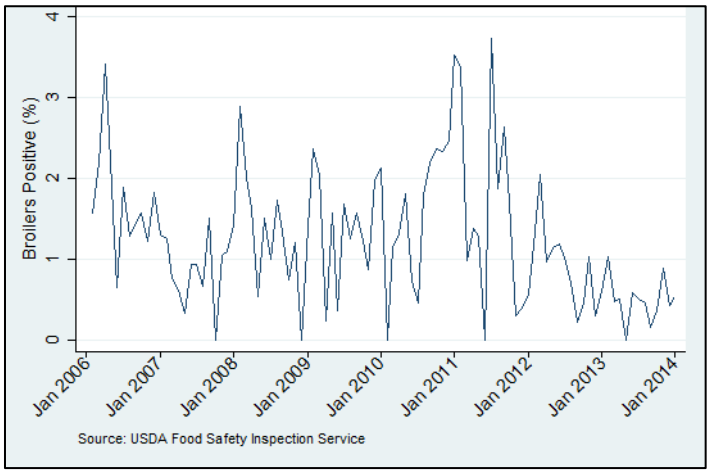
Counts of illness and incidence from *Salmonella* show local minima in February and all but one of the local maxima in August. Trends in the natural log of incidence (per million population) for *Salmonella* Enteritidis exhibit somewhat less seasonality than all other serotypes grouped together and are also somewhat less regular, as shown in Figure 3.

Figure 3. Monthly Ln(Incidence) of Salmonellosis by Serotype



I model the seasonality using a series of monthly dummy variables. For these dummies I delete February, so that the effects of each month are interpretable as relative to the month when the human cases are at their lowest level. In Figure 4, I present the FSIS data on the percentage of broilers positive for *S*E; the data show substantial variability, both seasonally and across years.

Figure 4. Monthly Percent of Broilers Positive for *Salmonella* Enteritidis



In Table IV, I present the results of regressions of human illness from *S*E, using dummy variables for months, a dummy variable for the period when FDA's egg rule was in effect, a measure of the percentage of broilers that test positive for *S*E, and the population of the area served by participating laboratories. In column A, a negative binomial model suggests that both the percentage of broilers that test positive for *S*E and the population have statistically significant effects on the count of human illness. This model hints at a negative effect of the egg rule on human illness—the coefficient is –0.12—but this effect is not statistically significant at the 90 percent confidence level.

Model A presumes a linear relationship between the percentage of broilers that test positive for *S*E and human illness. Specifically, a one percentage point increase in the percentage of broilers that test positive for *S*E is associated with about nine-tenths of a case per month, or a bit more than one lab-confirmed case per year. Such an increase in the percentage of broilers that test positive would be quite large relative to the variability in these data—the mean percentage of broilers that test positive for *S*E is 1.24 percent, with a standard deviation of 0.826 percent.

I present in Model B a similar regression using instead the natural log of the percentage of broilers that test positive for *S*E. (For this model, before taking the log, I arbitrarily assigned a value of 0.01 percent to each of the five months where no positive tests for *S*E were recorded.)

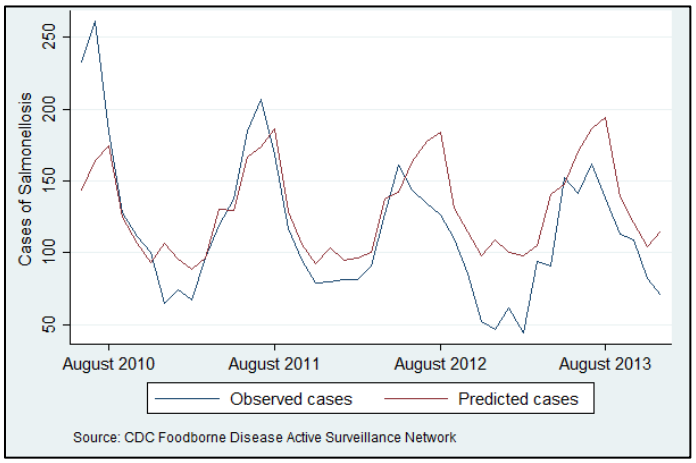
Table IV. *Salmonella* Enteritidis Illness Modeling Results

	A	B	C	D
Model	Negative binomial	Negative binomial	Negative binomial	Negative binomial
Broilers Positive for *S*E	0.0891*** (0.0254)	0.0449*** (0.0167)	0.0267 (0.0187)	NA
Population	1.20 *** (0.394)	0.960** (0.407)	1.47*** (0.354)	1.40*** (0.354)
Egg Rule Dummy	–.121 (0.0754)	–.0785 (.0778)	NA	NA
Log transformation of % of broilers positive for *S*E	No	Yes	No	NA
Comments	α = 0.0227 (se: 0.00555)	α = 0.0242 (se: 0.00550)	α = 0.0120 (se: 0.00424)	α = 0.0129 (se: 0.00426)
Robust Standard Errors	Yes	Yes	Yes	Yes
Log Pseudolikelihood	–415.96	–418.1	–217.1	–218.1
N	96	96	53	53

Note: The coefficients and standard errors for the population variable are the true values times 10^{-7}.

I use Model C in Table IV to develop counterfactual estimates of the incidence of lab-confirmed *S*E, making projections for the period after the rule is implemented. As shown in Figure 5, the projected values track the observed log of incidence of *S*E fairly well, with one exceptional period.

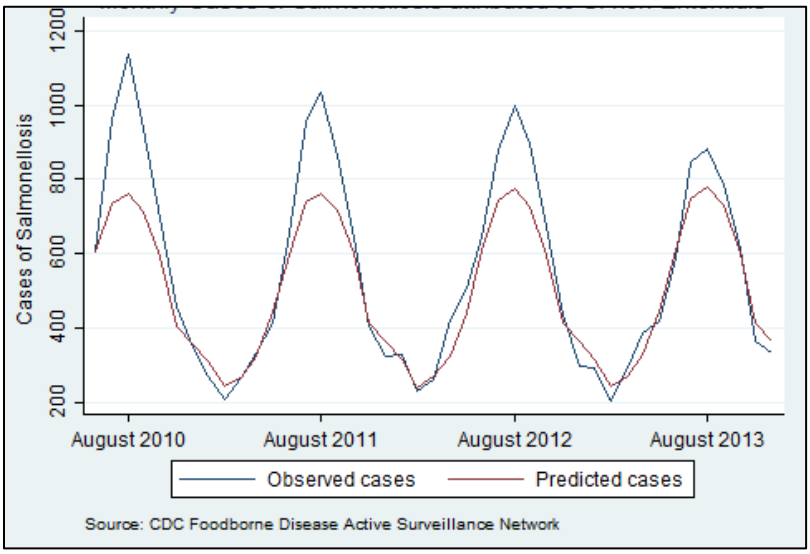
Figure 5. Monthly Cases of Salmonellosis Attributed to S. Enteritidis



There was an unusually sharp decline in observed cases relative to the forecast cases during the fall of 2012 and the winter of 2012-2013. Since this difference between observed and forecast cases does not persist at a comparable level, however, it is difficult to infer that it is a result of the rule. I am unaware of plausible explanations for this temporary gap between the actual and forecast cases.

I now expand the dataset to include incidence of illnesses from other *Salmonella* serotypes (as well as *S*E), thus allowing for a differences-in-differences approach. This approach comes at a cost, however. The large number of serotypes other than *Salmonella* Enteritidis and the variety of products on which they appear make it difficult to construct a measure comparable to the percentage of broilers that are positive for *S*E. I instead estimate a regression like Model D in Table IV for the monthly number of all *Salmonella* non-Enteritidis cases and calculate differences—the observed less the predicted number of cases. Figure 6 shows the observed and the predicted number of cases of *S*NE.

Figure 6. Monthly Cases of Salmonellosis Attributed to S. non-Enteritidis



I next pursue an approach that avoids making these out-of-sample calculations by instead using the prerule period as the counterfactual. To address seasonality, I pair each month during the period when the egg rule was in effect with an earlier month when it was not in effect. I pair months to maximize the number of such matched pairs. The earliest pair is August 2010 and August 2006, and the last pair is December 2013 and December 2009. To facilitate estimation of a mean effect expressed in percentage terms, I focus on the natural log of incidence (cases per million population); a visual inspection suggests this variable is normally distributed. This set of pairwise differences for ln(incidence of *S*E) and for ln(incidence of *S*NE) is summarized in the third row of Table V.

Table V. *Salmonella* Enteritidis vs. *Salmonella* non-Enteritidis

Comparison Method	Difference in Monthly ln Incidence of *S*E (Rule-Baseline)	Difference in Monthly ln Incidence of *S*NE (Rule-Baseline)	Differences-in-Differences
Observed: actual values 4 years earlier (N = 42)	.0197 (.0506)	.0235 (.0272)	–.0038 (.0574)

Note: Standard error in ( ).

I also conduct a similar differences-in-differences analysis using cases of illness from *Campylobacter*, which is frequently found on poultry and may be a second appropriate basis for comparison. The FSIS reported that the estimated national prevalence of *Salmonella* in chicken parts was 24.02 percent, while the estimated national prevalence of *Campylobacter* in chicken parts was 21.70 percent.[20] Using an approach comparable to the last row of Table V, I estimate that the decline in cases of *S*E is 5.3 percent with a standard error also equal to 5.3 percent. Thus the decline is not statistically significant, and the upper confidence limit on the effect is about 15.9 percent. *Campylobacter* may be, however, less appropriate for comparison than *Salmonella* non-Enteritidis. The two pathogens exhibit different seasonalities. The CDC reports that the local maxima for cases of *Campylobacter* occur in July rather than in August.[29] In addition, there may be differences between these pathogens in how cases of human illness are acquired. The CDC reports that the percentage of outbreak-related illnesses thought to be foodborne is 81 percent for *Campylobacter* but only about 74 percent for *Salmonella*.[29] Thus I prefer to use *S*NE for comparison, although use of *Campylobacter* gives qualitatively similar results.

I also estimate two different regressions with a variable for illness from *S*E and *S*NE and a differences-in-differences term. Using a negative binomial regression with monthly data for the count of illnesses of *S*E and *S*NE. I do not find a statistically significant effect of the egg rule on the count of illness from *S*E. Specifically, as shown in column A of Table VI, this model gives an estimated reduction of about 0.08, with a standard error of 0.06. Switching instead to the natural log of the incidence of illness, Model B yields an estimate for the effect of the rule on incidence of *S*E illnesses of –0.0739, with a standard error of 0.0979—also a result that is not statistically different from zero.

Table VI. Regression Models

	A	B
Model	**Negative binomial**	**Ln(incidence)**
S. Enteritidis Dummy	–1.46*** (0.0401)	–1.47*** (0.0632)
Population of FoodNet Area	2.59 (2.87)	NA
Dummy for Months the Egg Rule was in Effect	.0669 (.0597)	.0683 (0611)
Differences-in-Differences (Egg Rule*SE)	–0.0798 (0.0610)	–0.0739 (0.0979)
Monthly Dummies	Yes	Yes
alpha	.0346*** (0.00368)	NA
Standard Error Estimator	Robust	Newey
Pseudo R^2	0.220	NA
N	192	192

Note: The coefficients and standard errors for the population variable are the true values times 10^{-7}. The Newey estimator used a maximum lag of 3 months.

5. Discussion

FDA's egg rule appears to have had relatively small and statistically insignificant effects on human illness from *S*E. The standard error for the effect of the egg rule on incidence of *S*E relative to other *Salmonella* serotypes is 0.057 in Table IV, suggesting a 95 percent confidence interval extending as high as about 12 percent. The negative binomial regression shown in Table VI (col A) implies a 95 percent confidence limit of about 20 percent for the reduction in illnesses. Even this reduction is much less than FDA's best estimate of "eventual" reductions in incidence of 37 percent, and below FDA's estimate of "initial" benefits, a 32 percent reduction in illness, although it exceeds FDA's presumptive lower bound, 12 percent. The general result that the effect of FDA's egg rule is relatively small and statistically insignificant appears to be insensitive to a variety of alternative model specifications.

FDA's prospective estimate of the benefits of its final rule appears to be too large for other reasons as well. As demonstrated earlier, FDA's 2009 multiplier to calculate total cases from confirmed cases overstates total cases by about 18 percent. In addition, as documented

earlier, the social cost per case of salmonellosis has been recently estimated to be about 30 percent of the value that FDA used in its 2009 analysis.

Collectively these three findings suggest that FDA's prospective estimates of benefits were much too large, as shown in Table VII. Specifically, a retrospective estimate of benefits would be about $75 million annually. An upper bound reflecting the substantial uncertainty in effectiveness of the rule, but not the uncertainty in the multiplier or the cost of illness, would be about $187 million annually. A probability distribution of the benefits of the egg rule that incorporates the uncertainty in the number of unconfirmed cases of illness per confirmed case and in the social cost per case of illness would reflect a broader set of possible values.

Although this analysis has not focused on a retrospective assessment of the costs of FDA's egg rule, I note that the retrospective estimates of benefits may well be less than the estimates of costs of the rule projected by FDA in 2009. Specifically, FDA estimated that the initial costs were about $88 million annually and the eventual costs were about $81 million annually. The finding that the estimated benefits are below or in the range of the prospective estimates of costs suggests there may be merit in revisiting some policies regarding egg safety. In light of the lack of evidence about the effectiveness of the rule, one might ask whether extant requirements imposed on small farmers are sensible. FDA's 2009 analysis estimated that the compliance costs per farm were quite high for the majority of regulated egg producers, which collectively are responsible for a small share of total egg production. In particular, FDA reported that compliance costs as a percentage of revenue would reach 3.9 percent for the 670 farms with between 20,000 and 50,000 hens and 8 percent for the 1,660 farms with between 3,000 and 20,000 hens. These farms represent more than a majority of all farms covered by the rule but produce only 17 percent of the total amount of egg production regulated by the rule.[(5)]

The real value of this retrospective analysis is in the light that it sheds on the forgone benefits of the rule. The egg rule simply failed to bring about the public health gains that FDA had forecast. Thus it serves as a cautionary note to federal regulators that regulating without careful monitoring and evaluation of the effects of regulations may lead to an undeserved sense of satisfaction. Regulatory success should not merely be the issuance of a new regulation or effective enforcement of a new rule. In addition, it must include an unflinching look at whether the regulation achieved its goals, and if not, what alternative approaches might be more effective, and / or more cost-effective, at doing so. Food safety regulators to date have not hit the mark in this regard. In light of the wave of new food safety regulations expected as part of implementation of FSMA, FDA and other food safety regulators need to be much more attentive to measuring the actual effects of their rules.

Regarding prospective analysis, food safety agencies should focus more on pilot studies and field tests to collect information about the effects of their regulations. These pilot studies and field tests should be rigorous, involving random assignment. They should be comprehensive, covering all key regulatory provisions—that is, those that are key to estimates of costs, effectiveness, or benefits. And they should be thorough, in other words looking not only at the occurrence of the hazard or pathogen but also at changes in risks that matter to people, especially risks related to health and safety. Rules unsupported by such studies should be subject to extra special scrutiny as proposals and draft final rules, by the Department of Health and Human Services, the Office of Management and Budget, and Congress.

At the time a rule is issued, the regulatory agency should also issue a plan to monitor or track its effectiveness—a goal consistent with EO 13563 and the Government Performance and Results Act. This plan should identify metrics to assess whether the rule is delivering the beneficial effects (or imposing the costs) consistent with prior estimates and lay out specific steps to ensure that those metrics are publicly available on a timely basis. In the case of FDA's egg rule, this plan should have identified an appropriate comparison pathogen, such as *S*NE, as well as procedures for public access to the FoodNet data. It should also have noted that existing USDA farm surveys are not adequate to make statistical inferences about disproportionately large effects of FDA's egg rule on small egg producers and, accordingly, sought an expansion of USDA's sampling of those farmers, at least for a few critical years. Finally, in light of the relative ease of the differences-in-differences approach pursued here, it should have offered periodic reporting of such results.

Implementing these recommendations would entail resources and effort. But it might help avoid the current situation, where one of the most common foodborne pathogens, emanating from a single specific class of facilities and first targeted by public health officials nearly two decades ago, sickens scores of thousands of Americans annually, without any apparent reaction by policymakers. Perhaps therein lies the key lesson of this retrospective analysis. If regulators do not regularly assess the effects of extant rules, they may wrongly believe that a rule, once issued, has eliminated most of the problem it sought to address, even when a more careful look would point to the opposite conclusion.

Table VII. Retrospective Adjustments to FDA's Benefits Estimate for the Egg Rule

		FDA's Prospective Estimates	Revised or Retrospective Estimate	
			Best estimate	Upper bound
Total Annual Number of *SE* Cases from US Exposure		215,140 cases	175,600 cases	
Effectiveness of the Rule in Reducing Illness	Eventual cases avoided annually	79179 cases (37 percent)	NA	NA
	Initial cases avoided annually	68800 cases (32 percent)	0.08 (se: 0.06)	0.20
Social Cost of Typical Case of Human Illness from *SE*		$17,900/case	$5,337/case	
Annual Aggregate Benefits	"Eventual" Estimates	$1.42 billion	NA	NA
	"Initial" Estimates	$1.23 billion	$75 million	$187 million

6. Conclusion

Federal food safety regulations, if effective, can substantially reduce the number of cases of illness from foodborne pathogens, which have been estimated to be tens of millions of cases of illness annually. I am unaware of rigorous retrospective analyses by federal agencies of the costs, effectiveness, or benefits of federal food safety regulations, despite calls for such analyses in President Obama's executive orders. This paper explores FDA's earlier prospective estimates of the benefits of its egg rule. It suggests FDA's 2009 estimates of the benefits of its egg rule were much too high. Using CDC's data on human cases of foodborne illness linked to *Salmonella*, I evaluate whether FDA's rule reduced cases of illness from *Salmonella* Enteritidis. I use a differences-in-differences approach to estimate the effects of FDA's egg rule on human illness from *Salmonella* Enteritidis, in light of FDA's estimate in 2009 that its rule would reduce 79,000 cases of illness annually. I am unable to reject a hypothesis of no reduction in illness but can reject a reduction of 12 percent in incidence at the 95 percent confidence level. This reduction is approximately the lower bound of FDA's 2009 prospective estimate of effectiveness. Refining FDA's 2009 estimate to reflect improvements in the unit cost of illness from *Salmonella*, and the multiplier for the number of unobserved cases for every confirmed case, suggests that the benefits of FDA's 2009 rule may be less than or more than the prospective estimate of costs. This analysis illustrates the importance of measuring and seeking to improve the actual effects of federal regulation.

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Appendix

In September 2014, FDA issued proposed supplemental rules for four rulemakings regarding food safety.(2) Only the first rulemaking, which would address produce safety, contained quantitative estimates about the expected improvements in public health.

1. Proposed Supplemental Rule for Produce Safety[3]
2. Proposed Supplemental Rule for Preventive Controls for Human Food
3. Proposed Supplemental Rule for Preventive Controls for Animal Food
4. Proposed Supplemental Rule for Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals

Other recent FDA rulemakings include four other proposed rules and one final rule.(2) FDA did not provide quantitative estimates of improvements in public health as part of these rulemakings.

1. FSMA Proposed Rule on Sanitary Transportation of Human and Animal Food, published January 31, 2014
2. Proposed Rule for Focused Mitigation Strategies to Protect Food Against Intentional Adulteration, published December 20, 2013
3. Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, published October 25, 2013
4. Proposed Rule: Accreditation of Third-Party Auditors, published July 26, 2013
5. Final Rule: Record Availability Requirements: Establishment, Maintenance, and Availability of Records, published April 3, 2014

[3] The notice of proposed rulemaking contained an estimate that this rule as amended would reduce 1.57 million cases of illness annually (Fed Regist. 79:58435).