

# A retrospective review of the economic impact of the food and drug administration's proposed egg rule

Travis Minor\*, Matt Parrett

*Food and Drug Administration, Office of the Commissioner, 5100 Paint Branch Parkway, College Park, MD 20740, USA*

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## Abstract

Using novel 1998–2008 data collected by the Centers for Disease Control and Prevention on foodborne illnesses and outbreaks, we test using a difference-in-differences approach whether the Food and Drug Administration's proposed rule entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production" decreased the number of *Salmonella* illnesses associated with the consumption of shell eggs. We find that this rule led to a reduction in the number of *Salmonella* illnesses of between 308 and 434 illnesses per year, which we attribute to a reduction in the number of outbreaks associated with egg-containing products rather than a reduction in the average number of illnesses reported in each outbreak.

*JEL classifications:* H11, I18, Q18

*Keywords:* Difference in differences; Egg; Federal regulation; Foodborne illness; *Salmonella*

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## 1. Introduction

In 2004, the Food and Drug Administration (FDA) published a proposed rule titled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production" (the Proposed Egg Rule; Food and Drug Administration, 2004). In it, the FDA proposed to require shell egg producers to implement a number of measures aimed at preventing *Salmonella* Enteritidis (SE) contamination of eggs<sup>1</sup> on farms, stating that "ultimately, we expect that the proposed requirements in this rule will generate public health benefits through a decrease in the numbers of SE-associated illnesses and deaths caused by consumption of shell eggs." These proposed on-farm SE prevention measures, which do not apply to producers who sell all of their eggs directly to consumers or producers with fewer than 3,000 laying hens, include provisions for procurement of chicks and pullets (young chickens and hens); a biosecurity program; a pest and rodent control program; cleaning and disinfection of poultry houses that have had an environmental sample or egg test positive for

SE; refrigerated storage of eggs at the farm; and required testing of the environment for SE in poultry houses.

In this article, we test using a difference-in-differences approach whether the Proposed Egg Rule decreased the number of *Salmonella* illnesses and outbreaks caused by the consumption of shell eggs using novel 1998–2008 data on foodborne illnesses and outbreaks by commodity and pathogen collected by the Centers for Disease Control and Prevention (CDC). Although the Proposed Egg Rule is geared towards specifically preventing SE, the controls put in place by the rule likely aid in the prevention of other *Salmonella* serotypes.<sup>2</sup> Thus, in our analysis, we look at the effect of the Proposed Egg Rule on measures of *Salmonella* illnesses and outbreaks that include a wide array of *Salmonella* serotypes.

Note that because of the coverage of the CDC data used in this article (1998–2008), we are unable to examine the impact of either the Egg Rule Advanced Notice of Proposed Rulemaking (ANPRM) or the Final Egg Rule on *Salmonella* illnesses and outbreaks caused by the consumption of shell eggs.<sup>3</sup> That we end up finding an effect of the Proposed Egg Rule, however,

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\*Corresponding author. *Email address:* Travis.Minor@fda.hhs.gov (T. Minor)

### Data Appendix Available Online

A data appendix to replicate main results is available in the online version of this article.

<sup>1</sup> Outbreaks associated with *Salmonella* are linked most commonly to eggs and poultry (Gould et al., 2013).

<sup>2</sup> There are various "types" of *Salmonella*, referred to as serotypes or servovars. The *Salmonella* serotype which causes the highest number of infections is SE (Centers for Disease Control and Prevention, 2016).

<sup>3</sup> The first stage of the rulemaking process is the ANPRM. An ANPRM is essentially an announcement to the public that the agency authoring the ANPRM is interested in making a rule. There is typically a comment period associated with an ANPRM, whereby the public is given the opportunity to

is not surprising as there is evidence to suggest that the public responds to Proposed Rules. For example, both McDonald's, in September 2012, and Starbucks, in June 2013, among other restaurants, began posting calorie counts on their menus following the publication of the FDA's Proposed Menu Labeling Rule in April 2011, presumably in anticipation that the rule would eventually be made final, which it was in November 2014 (Strom, 2012; Thrasher, 2013).

To the best of our knowledge, we are the first to examine the impact of the Proposed Egg Rule. Related work has focused almost exclusively on the effect of the United States Department of Agriculture Food Safety Inspection Service's (USDA FSIS) 1996 pathogen reduction/hazard analysis and critical control point system final rule on *Salmonella* illnesses and outbreaks (Nganje et al., 2006, 2007; Ollinger and Moore, 2008). Our work is important from a policy standpoint as it informs the economic impact analysis of the Final Egg Rule, referred to as the Final Regulatory Impact Analysis (FRIA). A FRIA consists of estimates of a rule's costs and benefits and by Presidential Executive Order is a required part of the regulation promulgation process, especially for rules that are determined to be significant regulatory actions.<sup>4</sup> Using our estimates of the Proposed Egg Rule's effect on *Salmonella* illnesses associated with the consumption of shell eggs, we reevaluate the benefits of the Final Egg Rule that were estimated by the FDA in the Final Egg Rule FRIA.

The layout of this article is as follows. Section 2 provides a description of the data used in our analysis. Section 3 discusses our estimation methodology. Section 4 presents results and Section 5 concludes.

## 2. Data description

The data used in this analysis are primarily from outbreak reports collected by the CDC from 1998 to 2008. The data, which

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send written comments to the agency authoring the ANPRM about the rule in question. The second stage of the rulemaking process is the Proposed Rule. A Proposed Rule clearly defines and makes a case for the rule in question. Like with an ANPRM, there is a comment period associated with a Proposed Rule. The third stage of the rulemaking process is the Final Rule. Only a Final Rule carries legal authority. That is to say, the public is not legally compelled to adhere to anything promulgated in either an ANPRM or Proposed Rule. ANPRMs, Proposed Rules, and Final Rules are all published in the *Federal Register*. Final Rules are also published in the *Code of Federal Regulations*. The Egg Rule ANPRM was published on May 19, 1998, the Proposed Egg Rule was published on September 22, 2004, and the Final Egg Rule was published on July 9, 2009.

<sup>4</sup> Presidential Executive Order 12866 defines a significant regulatory action as any regulatory action that is likely to result in a regulation that may (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

originate from multiple state, local, and territorial public health agencies, are compiled and made available to the public through the National Outbreak Reporting System (NORS). Information such as the date, location, number of people who became ill, the food implicated in the outbreak (if any is determined to be), and the implicated pathogen (if any is determined to be), are all reported in this database (Centers for Disease Control and Prevention, 2011). Although reporting is voluntary, it is likely that the most serious foodborne illness incidents (those which are felt widely in the population) are catalogued by these data (Jones et al., 2013). This is because the larger foodborne outbreaks are more likely to produce at least one severe case which results in hospitalization and, thus, identification of a pathogen (Centers for Disease Control and Prevention, 2011). In total, the NORS database reports 13,352 outbreaks and 271,974 illnesses from the years 1998 to 2008 (Painter et al., 2013).

The NORS data do not readily lend themselves to direct analysis. First, because all outbreak investigations do not result in a complete collection of information, there is a substantial amount of missing information within the full database. Only about 37% (4,887) of all outbreaks are able to implicate a food vehicle (Painter et al., 2013). Second, of those outbreaks that do report a food vehicle, it may range from something very simple, such as lettuce or tomatoes, to something more complex, such as lasagna or apple pie, or even to something that completely defies classification, such as "multiple foods" or "unspecified." To aid in the analysis of the NORS data, Painter et al. (2013) applies a standard food commodity attribution to these data, specifically with regards to the complex foods implicated. In their study, Painter et al. (2013) were able to distribute all complex food outbreaks among a standard set of 17 food commodities (products). The products are leafy vegetables, dairy, fruits/nuts, poultry, vine/stalk vegetables, beef, eggs, pork, grains/beans, root vegetables, mollusk, fish, oils/sugars, crustacean, sprout vegetables, game, and fungi vegetables. Utilizing the distribution of each pathogen from its single commodity outbreaks, and applying common recipes for the complex food commodities implicated, the study attributes the illnesses, hospitalizations, and deaths associated with each food commodity implicated in the NORS database to one or multiple of the 17 standard food categories. After excluding data with missing values or unclassifiable foods, they compile a data set of 4,589 outbreaks (34% of total outbreaks) and 120,321 illnesses (44% of total illnesses) that occurred between 1998 and 2008.

Using the data compiled by Painter et al. (2013), we construct a pseudo-panel of the 17 mutually exclusive food commodities identified in their study. This allows us to examine trends in outbreaks, illnesses, and, most importantly, pathogen-specific illnesses attributable to each food commodity over the 11-year period. Beginning with the 4,589 individual outbreaks, we aggregate the data by year and food commodity to create a pseudo-panel of 187 observations (= 11 years × 17 food commodities). Summary statistics of our aggregated pseudo-panel are presented in Table 1 and reveal that approximately 159 *Salmonella* illnesses and roughly 5 *Salmonella* outbreaks

Table 1  
Summary statistics

	Mean	Standard deviation	Minimum	Maximum
<i>Salmonella</i>				
Illnesses	158.74	222.20	0.00	1,687.18
Outbreaks	4.69	5.26	0.00	30.73
Average illnesses	31.88	38.01	0.00	305.41
Key measures				
Egg-containing product*FDA treatment	0.02	0.15	0.00	1.00
FDA treatment	0.36	0.48	0.00	1.00
Egg-containing product	0.06	0.24	0.00	1.00
Price and volume measures				
Consumer price index	1.33	0.97	0.38	4.13
Producer price index	144.43	45.21	61.10	334.60
Consumer expenditures (\$)	214.29	103.18	32.00	507.00
Food available (billion/lbs.)	26.26	26.97	0.06	84.58
Import volume (billion/lbs.)	9.72	6.45	0.00	30.37
Import value (billion/\$)	5.70	3.75	1.13	13.91
National measures				
Temperature (°F)	53.52	0.55	52.31	54.32
Precipitation (inches)	29.79	1.72	27.73	32.97
Palmer Z drought index	-0.12	0.75	-1.35	1.39
Population (millions)	290.68	8.97	276.12	304.80
Number of farms (millions)	2.15	0.04	2.09	2.20
Other regulations				
FDA retail	0.73	0.45	0.00	1.00
Education campaign	0.82	0.39	0.00	1.00
USDA retail	0.91	0.29	0.00	1.00

Notes: All summary statistics contain 187 observations. Summary statistics for each commodity are identical (refer to egg-containing product summary statistics) and so are not presented.

occurred annually across all product categories.<sup>5</sup> Looking at average illnesses, defined as the number of *Salmonella* illnesses divided by the number of outbreaks, Table 1 indicates that an average *Salmonella* outbreak is comprised of about 32 *Salmonella* illnesses. We present figures on the three outcomes of interest graphed over the 1998–2008 time period. Fig. 1 shows the annual incidence of *Salmonella* illnesses related to egg-containing products. From the graph, we see a dramatic drop in illnesses from 2003 to 2004, and this lower level of illnesses seems to persist throughout the data.<sup>6</sup> However, it also appears that this

<sup>5</sup> Illnesses and outbreaks can assume non-whole number values in our data. This is due to Painter et al.'s aggregation methodology, in which they assume that a single illness or outbreak attributed to multiple food commodities is distributed among the commodities. For example, if they are presented with a single outbreak, consisting of nine illnesses, and which is attributed equally to two food commodities, they would evenly split the illnesses (4.5 per commodity) and the outbreaks (0.5 per commodity) across the affected commodities. The purpose of this methodology is that it preserves the total number of illnesses and outbreaks contained in the data set.

<sup>6</sup> Although it does not appear in our graph or data, there was an outbreak of *Salmonella* illnesses related to egg products in 2010 that was larger in scope than many of the reported totals in our observed years. In total 1,939 cases of

downward trend may have started sometime before 2004, following the peak in 2001. Fig. 2 which graphs the number of *Salmonella* outbreaks related to egg-containing products, tells a similar story, with outbreaks falling post 2004 and a peak incidence around the year 2000. Finally, Fig. 3 which graphs the average number of *Salmonella* illnesses per egg-related outbreak, shows an all-time low number of illnesses per outbreak in 2004, following a peak in the year 2001. However, these levels are not maintained in subsequent years. Together, the figures seem to indicate that something different was going on around the year 2004, but from these figures alone we cannot definitively say that the publication of the Proposed Egg Rule in 2004 had a significant effect on any of the outcomes.

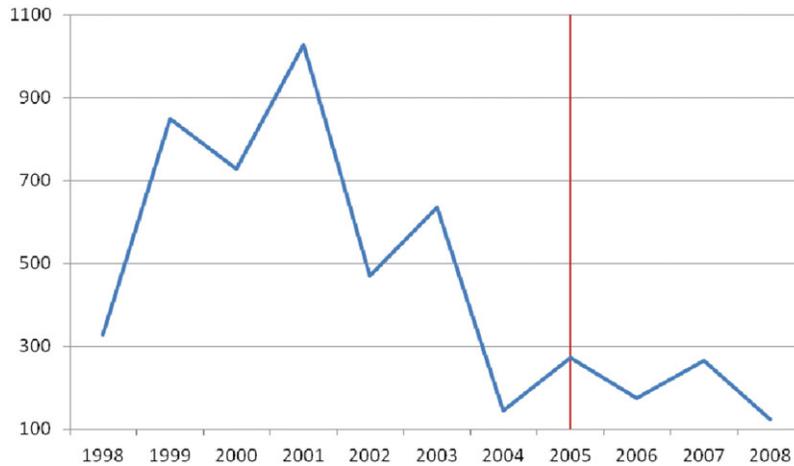
We created an indicator variable for each of the 17 individual food commodities comprising the data. Table 1 reveals that roughly 6% (1/17) of the data are composed of egg-containing products. Because we have a balanced panel of food commodity variables over time, each of the other product specific indicator variables, referred to collectively as the “Product Fixed Effects,” will have the same summary statistics as those associated with egg-containing products.

In addition, we created an indicator variable for each pathogen present in the data, which are summarized in Table 2 and referred to collectively as the “Pathogen Fixed Effects.” Of primary interest to this study is the indicator variable for any *Salmonella*-associated illness, which has a mean value of 0.93. Thus, of our 187 food commodity, year observations, 93% of them are associated, at least partially, with *Salmonella*-driven foodborne illnesses and outbreaks. This is interesting, as it easily outpaces all of the other identified pathogens in the data, with only *Staphylococcus*, *Clostridium perfringens*, and *Bacillus cereus* coming close with means of 81%, 78%, and 74%, respectively. This finding, however, is not surprising. Scallan et al. (2011) estimate that *Salmonella* is one of the most prevalent foodborne illnesses in the United States, with an estimated 1.03 million cases per year.<sup>7</sup> In addition, hospitals, clinics, and foodborne outbreak investigators are readily equipped and regularly test to diagnose *Salmonella* illnesses when signs and symptoms present themselves, whereas other pathogens are much less likely to be identified correctly, either at the point of contamination or in a medical setting, because of lack of regular testing equipment and prevalence of the disease itself. Finally, because *Salmonella* is relatively easily diagnosed, it is much more likely to be associated with foodborne illnesses where the specific food vehicle is not identified, causing it to be associated with multiple food commodities in the data.

Table 1 also summarizes data we collected on various price, volume, and national measures, as well as other regulations,

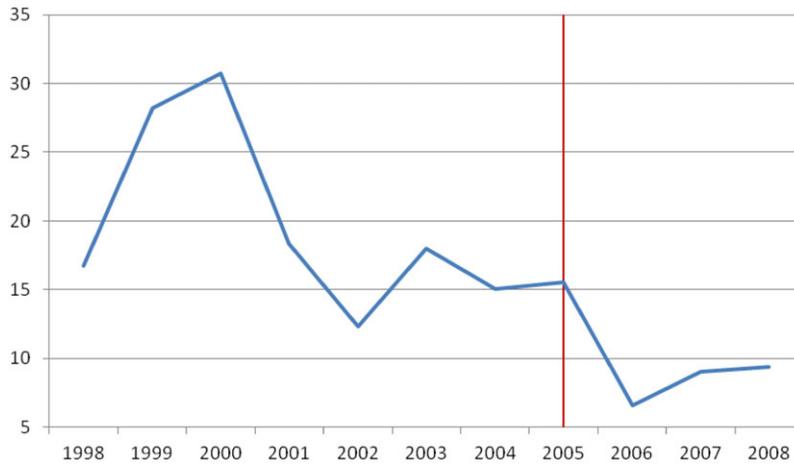
*Salmonella* were linked to shell eggs. However, besides this single outbreak, data from 2009 to 2011 appear to indicate a continuing trend of much lower incidences of *Salmonella* outbreaks and illnesses related to egg-containing products. Unfortunately, though, because unlike the data we use in our analysis these data are not attributed to specific food categories, we are unable to include them in our analysis.

<sup>7</sup> *Clostridium perfringens* has a similar estimate of 845,024 cases per year.



Notes: FDA's Proposed Egg Rule was published in 2004, and is represented here by a solid vertical line taking effect in 2005.

Fig. 1. Annual *Salmonella* illnesses from egg-containing product outbreaks.



Notes: FDA's Proposed Egg Rule was published in 2004, and is represented here by a solid vertical line taking effect in 2005.

Fig. 2. Annual *Salmonella* outbreaks from egg-containing products.

which might affect the occurrence or magnitude of a *Salmonella* illness or outbreak. These measures are described in greater detail in Section 3 of the article, where they serve as control variables.

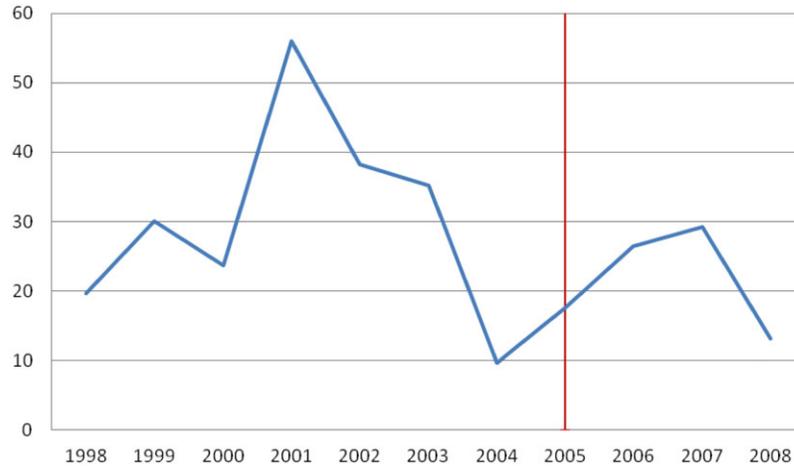
### 3. Estimation methodology

To estimate the effect of the Proposed Egg Rule on the number of *Salmonella* illnesses and outbreaks caused by the consumption of shell eggs, we adopt a difference-in-differences approach, as popularized by Card and Krueger (1994). They, and Kramarz and Philippon (2001) and Dube et al. (2010), examined the effect of minimum wage laws on various measures of human capital by exploiting geographic variation. However, a number of new studies, including Autor (2003), Zimmerman

(2003), and Edin et al. (2003), among others, have begun to apply this methodology to a variety of natural experiments, outcomes, and control groups.

In a natural experiment, a treatment is applied to one group, but not to a second, comparable group, the latter of which is referred to as the control group. In our case, the treatment is the publication of the Proposed Egg Rule, the treated group is all egg-containing products, and the control group is all other products. Given this setup, we estimate various specifications of the following econometric model:

$$\begin{aligned}
 Y_{i,t} = & \alpha_0 + \alpha_1 FDA\ Treatment_t + \alpha_2 Egg \\
 & -Containing\ Product_i + \alpha_3 FDA\ Treatment_t * Egg \\
 & -Containing\ Product_i + \alpha_4 X_{i,t} + \varepsilon_{i,t}.
 \end{aligned} \tag{1}$$



Notes: FDA’s Proposed Egg Rule was published in 2004, and is represented here by a solid vertical line taking effect in 2005.

Fig. 3. Annual average *Salmonella* illnesses per egg-containing product outbreak.

Table 2  
Summary statistics for pathogen indicators

Pathogen	Mean	Standard deviation	Minimum	Maximum
<i>Anisakis</i>	0.01	0.07	0	1
<i>Bacillus cereus</i>	0.74	0.44	0	1
<i>Brucella</i>	0.02	0.15	0	1
<i>Campylobacter</i>	0.49	0.50	0	1
<i>Clostridium botulinum</i>	0.21	0.41	0	1
<i>Clostridium perfringens</i>	0.78	0.42	0	1
<i>Cryptosporidium</i>	0.04	0.20	0	1
<i>Cyclospora</i>	0.13	0.34	0	1
<i>E. coli, all</i>	0.65	0.48	0	1
<i>Giardia</i>	0.09	0.28	0	1
Hepatitis A	0.26	0.44	0	1
<i>Listeria monocytogenes</i>	0.14	0.35	0	1
Marine biotoxins	0.28	0.45	0	1
Mycotoxins	0.06	0.25	0	1
Other chemicals	0.58	0.50	0	1
Rotavirus	0.10	0.30	0	1
<i>Salmonella</i>	0.93	0.26	0	1
Sapovirus	0.01	0.10	0	1
<i>Shigella</i>	0.50	0.50	0	1
<i>Staphylococcus</i>	0.81	0.39	0	1
<i>Trichinella</i>	0.06	0.25	0	1
<i>Vibrio</i>	0.28	0.45	0	1
<i>Yersinia</i>	0.05	0.21	0	1

Notes: All summary statistics contain 187 observations. Norovirus is omitted from all estimates because it is perfectly collinear with respect to the outcome. That is, Norovirus illnesses are present in each year/commodity pair.

We consider three specifications of  $Y_{i,t}$  is the total number of *Salmonella* illnesses associated with food commodity  $i$  in year  $t$ , the total number of *Salmonella* outbreaks associated with food commodity  $i$  in year  $t$ , and the average number of *Salmonella* illnesses per *Salmonella* outbreak associated with food commodity  $i$  in year  $t$ .  $\alpha_0$  is the intercept term,  $FDA Treatment_t$  is

an indicator variable for the publication of the Proposed Egg Rule, and  $Egg-Containing Product_i$  is a food commodity indicator variable for egg-containing products. Because the Proposed Egg Rule was published late in 2004 (September 22), we assume that it does not begin to have an effect until 2005. Thus,  $FDA Treatment_t$  is equal to one in 2005, and all subsequent years, and zero otherwise.<sup>8</sup>

$X_{i,t}$  is a vector of price, volume, national, and other regulation controls, as well as product and pathogen fixed effects. The latter were described in Section 2 of the article.

The “Price and Volume Controls,” which vary at both the year and food commodity level, include the Consumer Price Index, the Producer Price Index, Consumer Expenditures, Food Available, Import Volume, and Import Value. The Consumer Price Index, Producer Price Index, and Consumer Expenditures, collected annually by the Bureau of Labor Statistics (BLS) for each food commodity, capture the variability in *Salmonella* illnesses or outbreaks that may occur as a result of the individual prices that consumers are faced with when purchasing each product (Bureau of Labor Statistics, 2014). For example, the relative increases in prices, captured by either the Consumer Price Index or Producer Price Index, may be important for the cross-price substitution consumers make between related goods. In this case, it could be that egg prices rise faster than dairy or vegetable prices, making them less desirable for consumers or intermediate good producers, thus making a large-scale *Salmonella* outbreak less likely to occur. Food Available, Import Volume, and Import Value, which are collected by the USDA Economic Research Service (ERS), capture any changes in *Salmonella* illnesses or outbreaks that may occur as a result of the specific food supplied to the average American consumer in each given year (United

<sup>8</sup> However, using, instead, 2004 as the effective year does not alter our conclusions.

States Department of Agriculture Economic Research Service, 2014a, 2014b).

The “National Controls,” which do not vary across products, include Temperature, Precipitation, the Palmer Z Drought Index, Population, and the Number of Farms. Temperature, Precipitation, and the Palmer Z Drought Index are all collected at the national level by the National Oceanographic and Atmospheric Administration and capture any weather anomalies that might contribute to the likelihood of a *Salmonella* illness or outbreak (National Oceanic and Atmospheric Administration, 2014). These controls may be important if, in any given year, the growing conditions were particularly good or poor for producing clean foods. For example, it could be that in a year with particularly low rainfall or high temperatures foodborne pathogens are much less likely to persist in a field or housing facility, thus lowering the chance of a pathogen spreading to the consumed food itself. The population of the United States and the total number of farms operating in the United States, which are collected by the USDA ERS, capture any effect related to the size of the United States food or agricultural market (United States Department of Agriculture Economic Research Service, 2014a).

The Proposed Egg Rule was not the only rule implemented to prevent *Salmonella* illnesses and outbreaks during the time period covered in this article. Thus, we control for a number of retail-level egg safety measures, collectively referred to as “Other Regulations,” which were enacted prior to the publication of the Proposed Egg Rule. For example, the USDA FSIS issued a final rule in August 1998 requiring the refrigeration and labeling of eggs during transport and storage when packed for the ultimate consumer (United States Department of Agriculture, 1998). We control for this using the indicator variable USDA Retail, which is equal to one if the year is 1999 or later and zero otherwise. In addition, in December 2000, the FDA issued a final rule requiring the labeling and refrigeration of eggs at retail establishments (Food and Drug Administration, 2000). We control for this using the indicator variable FDA Retail, which equals one if the year is 2001 or later and zero otherwise. Finally, the FDA initiated an egg safety education campaign in July 1999, following the release of their egg labeling and refrigeration proposed rule which, as described above, became final in 2000 (Food and Drug Administration, 2004). As part of the campaign, the FDA issued, and continues to issue, fact sheets and other materials aimed at educating the public about egg safety (Food and Drug Administration, 2004). We control for this using the indicator variable Education Campaign, which equals one if the year is 2000 or later and zero otherwise. Where the Proposed Egg Rule differs from these measures is that it is the first federal regulation aimed at reducing the presence of *Salmonella* in eggs during *production*. Besides the Proposed Egg Rule, we are unaware of any other producer-level measures which we are able to control for that were enacted during the time period considered in our analysis (1998–2008).

Finally,  $\varepsilon_{i,t}$  is the idiosyncratic error term. We are mainly interested in the effect of the Proposed Egg Rule, hence our

primary interest is in  $\alpha_3$ , the coefficient on  $FDA\ Treatment_i * Egg-Containing\ Product_i$ .

#### 4. Results

Table 3 presents estimates of the effect of the Proposed Egg Rule on egg-related *Salmonella* illnesses, *Salmonella* outbreaks, and average *Salmonella* illnesses per outbreak. Model 1 only includes the core difference-in-differences variables ( $FDA\ Treatment * Egg-Containing\ Product$ ,  $FDA\ Treatment$ ,  $Egg-Containing\ Product$ ). The results from Model 1 reveal that the publication of the Proposed Egg Rule reduced egg-related *Salmonella* illnesses by about 434 cases per year, as identified by  $FDA\ Treatment * Egg-Containing\ Product$ . In addition, the statistically insignificant coefficient on  $FDA\ Treatment$ , which measures the effect of the Proposed Egg Rule on *Salmonella* illnesses associated with non-egg products, lends credence to our control group. Subsequent models add additional control variables to see how robust our finding is when other factors potentially influencing the occurrence or magnitude of a *Salmonella* outbreak are taken into account.

Model 2 adds to Model 1 indicators for the pathogens implicated and the food commodities identified by the outbreak investigation, price and volume measures, national statistics for temperature, precipitation, and other factors that may have affected growing conditions, and indicators associated with each of the three other regulatory actions (USDA Retail, FDA Retail, and Education Campaign) which took place during our analyzed timeframe. Estimates from Model 2 reveal that the Proposed Egg Rule reduced the number of *Salmonella* illnesses associated with egg-containing products by a somewhat smaller 308 cases each year. Because Model 2 adds a number of control variables that were likely impacting the occurrence and severity of *Salmonella* illness outbreaks related to all products, its results are preferred to the uncontrolled results of Model 1.

Taken together, Models 1 and 2 indicate that the Proposed Egg Rule reduced the number of *Salmonella* illnesses associated with egg-containing products by between 308 and 434 cases per year. As this was the stated goal of the regulation, these estimates show that the Proposed Egg Rule was effective, at least to some degree; what they do not show is how this goal was achieved.<sup>9</sup> We explore this further by looking at the number of *Salmonella* outbreaks and the average composition of an outbreak to see if this reduction in illnesses is simply a function of reducing the number of outbreaks or if, instead, the Proposed Egg Rule changed in some meaningful way the size of outbreaks.

The second set of results in Table 3 presents the effect of the Proposed Egg Rule on the number of egg-related *Salmonella*

<sup>9</sup> We additionally perform all analyses excluding outlier observations according to Cook's D stat, DFITS stat, and DFBETA stats. Results are not substantially different from those presented in the full analysis and are available upon request.

Table 3

The effect of the proposed egg rule on *Salmonella* illnesses, outbreaks, and average illnesses from egg-containing products

	Illnesses		Outbreaks		Average Illnesses	
	(1)	(2)	(1)	(2)	(1)	(2)
<i>FDA Treatment*Egg-Containing Product</i>	−434.23*** (118.49)	−307.73** (120.71)	−8.89*** (3.01)	−7.28** (2.92)	−8.89*** (3.01)	8.01 (16.45)
<i>FDA Treatment</i>	44.83 (36.53)	−29.95 (112.58)	−0.88 (0.59)	−0.68 (1.46)	−0.88 (0.59)	−2.11 (19.57)
<i>Egg-Containing Product</i>	474.38*** (109.12)	480.93 (372.14)	15.64*** (2.47)	−1.16 (4.32)	15.64*** (2.47)	44.69 (51.99)
<i>R</i> <sup>2</sup>	0.16	0.57	0.36	0.87	0.36	0.57
Additional controls						
Constant	Yes	Yes	Yes	Yes	Yes	Yes
Price and volume controls	No	Yes	No	Yes	No	Yes
National controls	No	Yes	No	Yes	No	Yes
Other regulations	No	Yes	No	Yes	No	Yes
Product and pathogen fixed effects	No	Yes	No	Yes	No	Yes

Notes: \*, \*\*, and \*\*\* represent significance at the 10%, 5%, and 1% levels, respectively. All estimations contain 187 observations. Numbers presented in parentheses are robust standard errors. Full regression results available upon request.

outbreaks. The estimates vary slightly in magnitude but overall reveal that the publication of the Proposed Egg Rule decreased the number of *Salmonella* outbreaks associated with egg-containing products by between seven and nine outbreaks per year, with the preferred specification, in Model 2, suggesting the more conservative change of just over seven fewer outbreaks per year after the Proposed Egg Rule.

The third set of results in Table 3 illustrates the effect of the Proposed Egg Rule on the average number of egg-related *Salmonella* illnesses per *Salmonella* outbreak. This could be important because a significant reduction here would indicate that the Proposed Egg Rule was primarily affecting the largest outbreaks (likely to be those outbreaks occurring from only the largest producers, who would be explicitly covered by a rule), causing those that were left to be smaller in scope and, therefore, less burdensome. Alternatively, a positive effect of the Proposed Egg Rule on the average number of illnesses per outbreak would suggest that outbreaks were becoming larger due to the Proposed Egg Rule, but this is unlikely unless outbreaks are simply growing larger over time in some manner that our control variables are unable to account for. Looking at Table 3, it seems that the Proposed Egg Rule did not affect the average number of illnesses from a given egg-related *Salmonella* outbreak. While Model 1 does show a statistically significant reduction in the average number of egg-related *Salmonella* illnesses per outbreak of about nine illnesses, as more controls are added this effect becomes insignificant.

## 5. Conclusion

Using a difference-in-differences estimator to examine the impact of the FDA's Proposed Egg Rule on the marketplace, we find evidence that the publication of this rule, which was geared towards preventing just a specific *Salmonella* serotype (*Salmonella* Enteritidis), did in fact lead to a reduction in the

overall number of *Salmonella* illnesses associated with egg-containing products. More specifically, the results from this study indicate that the FDA's Proposed Egg Rule reduced the number of *Salmonella* illnesses occurring from outbreaks related to egg-containing products by between 308 and 434 illnesses annually. Our results further reveal that this reduction is achieved through a reduction in overall outbreaks associated with egg-containing products, rather than a reduction in the average number of illnesses recorded in each outbreak. This suggests that the rules prescribed by the Proposed Egg Rule are being adopted across the industry, not simply by the largest producers.

This study could have significant implications for future policy decisions as it outlines a methodology to reevaluate a program's impacts and compare them to the costs that were incurred due to implementation. Using our estimates of the effect of the Proposed Egg Rule on the number of egg-related *Salmonella* illnesses, we reevaluate the effectiveness of the Final Egg Rule titled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (Food and Drug Administration, 2009). Using an estimated annual reduction in *Salmonella* illnesses of 371 (average of 308 and 434) from outbreaks alone and the underreporting multiplier<sup>10</sup> of 38 from the FDA's FRIA published as part of the Final Egg Rule yields a total of 14,098 prevented *Salmonella* illnesses annually. Assuming the same cost of illness (\$17,900) and cost to industry estimated by the FDA in the FRIA gives us a total reevaluated benefit of \$252 million (ranging between \$210 and \$295 million) annually, which greatly exceeds the approximate \$90 million in annual costs to industry estimated by the FDA in the FRIA. The reevaluated benefits estimated here can be thought of as a lower bound, as we are using estimates of the effect of the Proposed Egg Rule to compute them. The reason we do

<sup>10</sup> In this case, the multiplier is used to account for the underreporting and underdiagnosis biases in the national outbreak numbers.

this is because, as discussed previously, the time period covered by the CDC data used in this article (1998–2008) does not coincide with the timing of the publication of the Final Egg Rule (2009).

There are numerous advantages associated with the data used in this analysis, such as rigorous national collection techniques (Centers for Disease Control and Prevention, 2011) and pathogen-food pairings which make this type of analysis possible (Painter et al., 2013). However, the data and analysis are not without their limitations. First, the data were compiled and presented at a national level (if any specific region is indicated in the data, it is where the food was consumed, not grown or produced). This prevents the inclusion of any regional factors that may have influenced growing conditions or food quality, which could also be factors contributing to an outbreak. Second, the point of contamination of the product is rarely discovered and not disclosed in the data. This prevents the analysis from taking farm, manufacturing, transport, or home use as the primary cause of illness, all of which may influence the size or scope of the outbreak, but could have additional effects which are currently unexamined. Finally, our analysis considers only the effect of the Proposed Egg Rule and not the Final Egg Rule. Again, the latter, because it was published in 2009, lies outside of the time period covered by our data (1998–2008). Once additional data become available, future research should examine the impact of the Final Egg Rule on egg-related *Salmonella* illnesses and outbreaks.

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## Disclaimer

The usual disclaimer applies. The opinions and conclusions expressed in this article are solely the views of the authors and do not necessarily reflect those of the Food and Drug Administration.

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