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The economic impact of the Food and Drug Administration's Final Juice HACCP Rule ☆

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ABSTRACT

Using 1998–2008 data collected by the Centers for Disease Control and Prevention on foodborne illnesses and outbreaks, we examine the economic impact of the Food and Drug Administration's final rule titled "Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice" (the Final Juice Rule). Using a difference-in-differences approach, we find that the rule led to an annual reduction of between 462 and 508 foodborne illnesses associated with juice-bearing products. Furthermore, our reevaluated estimate of the rule's benefits compares favorably to its estimated cost.

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1. Introduction

The Food and Drug Administration (FDA) published a final rule in January 2001 titled "Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice" (the Final Juice Rule) aimed at ensuring the safe and sanitary processing of fruit and vegetable juices by requiring the application of HACCP principles to juice processing in the United States (U.S.) (Food and Drug Administration, 2001).[1] This rule, which became effective in January 2002,[2] was issued in the wake of a large number of documented foodborne illnesses associated with juice products, particularly in the 1990s (Food and Drug Administration, 1998; Kashtock, 2003/2004; Vojdani et al., 2008).[3] In this paper, we test using a difference-in-differences approach whether the Final Juice Rule decreased the number of foodborne illnesses associated with juice-bearing products in the U.S. using novel 1998–2008 data on foodborne illnesses and outbreaks by commodity and pathogen collected by the Centers for Disease Control and Prevention (CDC) and compiled by Painter et al. (2013). For purposes of this analysis, juice-bearing products refer to fruit and nut products.[4]

Our paper ties most closely to the literature on food safety standards, a big focus of which is foreign trade effects (e.g., Anders and Caswell, 2009; Ferro et al., 2015; Herzfeld et al., 2011; Jongwanich, 2009; Liu and Yue, 2012; Melo et al., 2014; Schuster and Maertens, 2015; Shepherd and Wilson, 2013). However, a number of studies in this literature examine the effect of food safety standards, most notably HACCP, on the microbiological quality of foods, finding that food safety standards are effective in improving the microbiological quality of the food or foods studied (e.g., Amoa-Awua et al., 2007; Cenci-Goga et al., 2005; Hong et al., 2008; Nada et al., 2012; Soriano et al., 2002; Wang et al., 2010). Regarding health effects, we know of just two studies, Asfaw et al. (2010) and Okello and Swinton (2010), which look at the effect of food safety standards on the health of the producer, and only one, Vojdani et al. (2008), which looks at the effect of food safety standards on the health of the consumer. Vojdani et al. (2008) examine the effect of the Final Juice Rule using CDC Foodborne Outbreak Reporting System data and find that fewer outbreaks associated with juice

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[1] HACCP is a preventive system of hazard control.

[2] The Final Juice Rule became effective for small and very small producers in 2003 and 2004, respectively.

[3] Juice-related foodborne illnesses include but are not limited to *E. coli* O157:H7, various strains of *Salmonella*, and *Cryptosporidium* (Food and Drug Administration, 1998).

[4] We focus on juice-bearing products (e.g., apples, oranges, ...) because the compiled data do not contain juice products per se (e.g., Brand X Orange Juice, Brand Y Apple Juice). We consider the effect of alternative classifications of juice-bearing products in Section 3 of the paper.

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products were reported following the rule's implementation. A major drawback of their study, however, is its lack of an identification strategy – it just looks at the number of juice-related outbreaks of foodborne illness pre- and post-implementation of the Final Juice Rule. As a result, the authors cannot with any confidence attribute their findings to the Final Juice Rule. In contrast, our identification strategy is based on a difference-in-differences approach.

This work is important from a policy standpoint as it informs the economic impact analysis of the Final Juice 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. Using our estimates of the Final Juice Rule's effect on foodborne illnesses associated with juice-bearing products, we reevaluate the benefits of the Final Juice Rule that were estimated by the FDA in the Final Juice Rule FRIA.

The layout of this paper is as follows. Section 2 provides a description of the data used in our analysis. Section 3 discusses our estimation methodology. Section 4 presents our results and Section 5 discusses those results. Section 6 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 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).[5] 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 raw NORS data do not readily lend themselves to direct analysis. First, given the raw nature of the data, cleaning and compiling them for use is no small feat. Second, 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 percent (4887) of all outbreaks are able to implicate a food vehicle (Painter et al., 2013). Third, 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'.

Painter et al. (2013) clean and compile the raw NORS data by distributing all simple and complex food outbreaks, for which there is a single implicated pathogen and the ingredients of the contaminated food(s) can be characterized, 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. For a simple food outbreak involving a particular pathogen, the authors allocate illnesses to the single implicated commodity. For example, if an outbreak of Pathogen X involving orange juice caused nine illnesses, then Painter et al. (2013) would allocate all nine illnesses to the fruits/nuts product category.

For a complex food outbreak involving a particular pathogen, the authors first apply a recipe to the complex food, the result of which is a list of simple foods that comprise the complex food. They then assign each of the simple foods to one of the 17 product categories listed above, the result of which is a list of affected product categories. To allocate illnesses to affected product category "p", the authors rely on the ratio of the number of illnesses caused by the particular pathogen across all product category "p" simple food outbreaks to the number of illnesses caused by the particular pathogen across all simple food outbreaks involving any of the affected product categories. For example, if an outbreak of Pathogen Y involving hamburgers caused 100 illnesses, Painter et al. (2013) would first apply a recipe to the hamburger, defining a hamburger, say, as consisting of beef (product category = beef), a bun (product category = grains/beans), tomato (product category = fruits/nuts), and lettuce (product category = leafy vegetables). They would then calculate the total number of illnesses caused by Pathogen Y across all simple food outbreaks involving each product category making up a hamburger, respectively. Suppose that the total number of illnesses caused by Pathogen Y across all simple food outbreaks involving the beef, grains/beans, fruits/nuts, and leafy vegetables product categories, respectively, are 500, 0, 300, and 200. From this, they would calculate each product category's percentage contribution to the total number of illnesses (1000). The beef product category's percentage contribution is 50 percent, the grains/beans product category's percentage contribution is 0 percent, the fruits/nuts product category's percentage contribution is 30 percent, and the leafy vegetables product category's percentage contribution is 20 percent. The authors would then use these percentages to allocate the 100 hamburger illnesses to each of the affected product categories that comprise a hamburger so that 50 illnesses are allocated to the beef product category, 0 illnesses are allocated to the grains/beans product category, 30 illnesses are allocated to the fruits/nuts product category, and 20 illnesses are allocated to the leafy vegetables product category.[6]

After excluding data with missing values or unclassifiable foods, Painter et al. (2013) compile a data set of 4589 outbreaks (34 percent of total outbreaks) and 120,321 illnesses (44 percent of total illnesses) that occurred between 1998 and 2008. Using

[5] These reports typically capture just a fraction of the actual number of foodborne illnesses. See footnote 18 for further detail.

[6] Painter et al. (2013) refer to this methodology of compiling the raw NORS data as the 'most probable' methodology. The authors also considered two additional methodologies, the 'minimum' methodology and the 'maximum' methodology. Under the 'minimum' methodology, Painter et al. consider only simple food outbreaks in their compilation, treating simple food outbreaks like in the above orange juice example. Thus, under the 'minimum' methodology in the hamburger example above, Painter et al. would assign zero illnesses to the Pathogen Y outbreak involving hamburgers, because a hamburger is a complex food. Under the 'maximum' methodology, Painter et al. consider both simple and complex food outbreaks in their compilation, treating simple food outbreaks like in the above orange juice example, but for complex food outbreaks assigning each product category comprising the complex food the full number of illnesses associated with the complex food itself, but only for product categories for which there has been at least one simple food outbreak related to the pathogen of interest. Thus, under the 'maximum' methodology in the hamburger example above, Painter et al. would assign 100 illnesses to *each* of the beef, fruits/nuts, and leafy vegetables product categories. Only the data associated with the 'most probable' methodology are publicly available. However, the 'most probable' is the data compilation methodology we prefer, because the 'minimum' data compilation methodology understates the number of foodborne illnesses and the 'maximum' data compilation methodology overstates the number of foodborne illnesses.

Table 1
Summary statistics.

	Full sample period				Pre-rule		Post-rule	
	Mean	S. D.	Min.	Max.	Mean	S. D.	Mean	S. D.
Outcome variable								
Foodborne illnesses	643.43	498.10	16.11	2267.69	690.12	493.42	616.75	500.87
Key explanatory variables								
Final Juice Rule ∗ Juice-bearing products	0.04	0.19	0.00	1.00	0.00	0.00	0.06	0.24
Final Juice Rule	0.64	0.48	0.00	1.00	0.00	0.00	1.00	0.00
Juice-bearing products	0.06	0.24	0.00	1.00	0.06	0.24	0.06	0.24
Price and volume controls								
Consumer price index	1.33	0.97	0.38	4.13	1.20	0.87	1.41	1.01
Producer price index	144.43	45.21	61.10	334.60	128.14	33.98	153.74	48.22
Consumer expenditures ($)	214.29	103.18	32.00	507.00	199.81	96.67	222.57	106.23
Food available (billion/lbs.)	26.26	26.97	0.06	84.58	25.57	26.70	26.65	27.23
Import volume (billion/lbs.)	4.86	3.23	0.00	15.19	4.11	2.58	5.29	3.48
Import value (billion/$)	5.70	3.75	1.13	13.91	4.47	2.98	6.40	3.97
National controls								
Temperature (°F)	53.52	0.55	52.31	54.32	53.80	0.39	53.36	0.57
Precipitation (inches)	29.79	1.72	27.73	32.97	29.28	2.17	30.08	1.33
Palmer Z drought index	−0.12	0.75	−1.35	1.39	−0.50	0.73	0.10	0.66
Population (millions)	290.68	8.97	276.12	304.80	280.78	3.46	296.34	5.59
# Farms (millions)	2.15	0.04	2.09	2.20	2.17	0.01	2.14	0.04

Notes: Full sample period summary statistics contain 187 observations; 68 for the pre-rule period (1998–2001); and 119 for the post-rule period (2002–2008). Summary statistics for each of the sixteen remaining products are identical (Mean = 0.06, SD = 0.24), and so are not presented. Juice-bearing products refer to fruit and nut products.

the publicly available data compiled by Painter et al. (2013), we construct a panel of the 17 mutually exclusive food commodities identified in their study. This allows us to examine trends in illnesses attributable to each food commodity over the 11 year period. Beginning with the 4589 individual outbreaks, we aggregate the data by year and food commodity to create a panel of 187 observations (= 11 years × 17 food commodities).[7] Summary statistics of our aggregated panel are presented in Table 1 and reveal that approximately 643 foodborne illnesses occurred annually across all product categories. Fig. 1 shows the annual incidence of foodborne illnesses associated with juice-bearing products, which reached their lowest point in 2002, the year in which the Final Juice Rule became effective.[8] Comparing the mean number of foodborne illnesses associated with juice-bearing products in the periods before and after the Final Juice Rule became effective reveals a decrease in foodborne illnesses of about one-third between these periods.

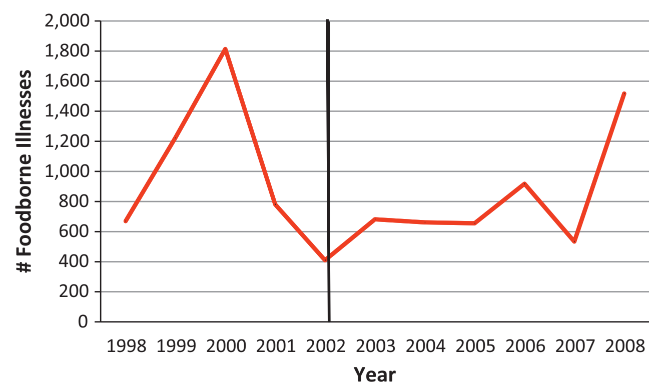

Fig. 1. Annual incidence of juice-bearing product foodborne illnesses. Notes: The vertical line at 2002 represents the effective date of the Final Juice Rule.

We created an indicator variable for each of the 17 individual food commodities comprising the data. Table 1 reveals that roughly 6 percent (= 11/187) of the data are comprised of juice-bearing products which, as stated earlier, refer to fruit and nut products. Because we have a balanced panel of food commodity variables over time (e.g., 11 observations per food commodity), each of the other product specific indicator variables, referred to collectively as the "Product Fixed Effects", will also account for approximately 6 percent of the total observations.

We also 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". Juice-related foodborne illnesses include but are not limited to *E. coli* O157:H7, various strains of *Salmonella*, and *Cryptosporidium* (Food and Drug Administration, 1998). Looking at Table 2, 65 percent, 93 percent, and 4 percent of our 187 food commodity, year observations are associated with these pathogens, respectively.

Finally, we collected data on various price, volume, and national measures which might affect the occurrence or magnitude of a

[7] Illnesses and outbreaks can assume non-whole number values in our data. This is due to the aggregate nature of the Painter et al. (2013) publicly available compiled data. Each of the initial 4589 rows of data represents an outbreak, associated with which is a total number of illnesses and a designation of which of the 17 food commodities are affected by the outbreak. Note that in the publicly available data, Painter et al. (2013) do not distribute the total number of illnesses across the affected product categories. Thus, to make the publicly available data operational, we distribute the total number of illnesses across the affected product categories evenly. For example, if confronted with a row of outbreak data revealing 11 illnesses affecting the product categories beef and fruits/nuts, we would assign 5.5 illnesses to the beef category and 5.5 illnesses to the fruits/nuts category.

[8] Fig. 1 provides motivation for the analysis, but it also suggests some anomalous behavior at the start and end of our observed data. The incidence for 1998 seems somewhat low, suggesting a dramatic increase from 1998 to 1999 and 2000; however, this seeming jump may exist for a few reasons. First, the outbreak reporting system received a major overhaul in 1998 which improved data collection methods substantially. The low point in 1998 may represent a transition period where reporting was not as comprehensive as it became. On the other hand, pre-1998 levels may be higher than those observed in this single year, suggesting a level much closer to the 1999 and 2000 levels of illness. Finally, outbreak data are admittedly sporadic, and drawing too much from a single year, such as 1998, the starting point of these data, may lead to some false conclusions. Without more data, it is difficult to say for sure. Additionally, 2008 suggests a large jump in observed illnesses, but, without extending the time horizon, it is impossible to tell if this is a one-year anomaly in the outbreak data, generated through one severe outbreak, or an upward trend that persists.

foodborne illness, and which are summarized in Table 1. The price and volume measures, which vary at both the year and food commodity level, include the consumer price index, the producer price index, and consumer expenditures, all of which are collected annually by the Bureau of Labor Statistics for each food commodity, and food available, import volume, and import value, all of which are collected by the United States Department of Agriculture Economic Research Service (USDA ERS). The national measures, which do not vary across products, include temperature, precipitation, and the Palmer Z drought index,[9] all of which are collected at the national level by the National Oceanographic and Atmospheric Administration, and population and the number of farms, both of which are collected by the USDA ERS.

3. Estimation methodology

We use a difference-in-differences approach to estimate the effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products.[10] The difference-in-differences estimator is most appropriate when evaluating the effect of a natural experiment, where a treatment is applied to one group, but not a second group (often noted as the control group). The treatment is the Final Juice Rule, the treated group is juice-bearing products, and the control group comprises the remaining product categories.[11] Given this setup, we estimate various specifications of the following econometric model using Ordinary Least Squares:

$$\begin{aligned} Y_{i,t} = {} & \alpha_0 + \alpha_1 \mathit{Final\,Juice\,Rule}_t\, x\, \mathit{Juice\text{-}Bearing\,Products}_i \\ & + \alpha_2 \mathit{Final\,Juice\,Rule}_t + \alpha_3 \mathit{Juice\text{-}Bearing\,Products}_i + \alpha_4 \boldsymbol{X_{i,t}} \\ & + \alpha_5 \boldsymbol{P_i} + \alpha_6 \boldsymbol{Z_t} + \varepsilon_{i,t} \end{aligned}$$

where $Y_{i,t}$ is the total number of foodborne illnesses by product-year, α_0 is the intercept term, *Final Juice Rule*$_t$ is an indicator variable equal to one in 2002 (the year in which the Final Juice Rule became effective) and beyond and zero otherwise, and *Juice-Bearing Products*$_i$ is an indicator variable for juice-bearing products which, as stated earlier, refer to fruit and nut products.[12] Note that the data used here are not granular enough to allow us to identify juice products per se within the juice-bearing product category. Thus, our estimates of the effect of the Final Juice Rule potentially capture both juiceborne and non-juiceborne illnesses associated with juice-bearing products (negative or positive spillover effects).[13]

$\boldsymbol{X_{i,t}}$ is a vector of price and volume controls, as well as pathogen fixed effects, $\boldsymbol{P_i}$ is a vector of product fixed effects, and $\boldsymbol{Z_t}$ is a vector of national controls, all of which were introduced in Section 2.[14] The price controls, which include the consumer price index, producer price index, and consumer expenditures, capture the variability in foodborne illnesses 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 juice-bearing product prices rise faster than related product prices, making them less desirable for consumers or intermediate good producers, thus making a large scale foodborne illness outbreak less likely to occur. The volume controls, which include food available, import volume, and import value, capture any change in foodborne illnesses that may occur as a result of the specific food supplied to the average American consumer in each given year (United States Department of Agriculture Economic Research Service, 2014a, 2014b). The construction of the pathogen and product fixed effects is discussed in full in Section 2. They are included to eliminate any pathogen or product specific heterogeneity that might impact our estimate of the effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products.

The national controls include temperature, precipitation, the Palmer Z drought index, population, and the total number of farms operating in the United States. Temperature, precipitation, and the Palmer Z drought index capture any weather anomalies that might contribute to the likelihood of a foodborne illness (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 capture any effect related to the

[9] The Palmer Z drought index is a measure of annual drought conditions. It is a scale of −4 to 4, where zero represents normal moisture conditions, −4 represents extreme drought, and 4 represents extremely high levels of moisture.

[10] Although we only look at the effect of the Final Juice Rule on the fruit and nut product category, it is possible that this rule also had an effect on other product categories. For example, root vegetables, such as carrots or beets, vine and stalk vegetables, such as celery, or leafy vegetables, such as kale or spinach, could all be affected. However, because the outbreaks associated with these kinds of juice are either very small or non-existent (see NORS database), it is unlikely that any changes will be observed by this analysis. As a robustness check, we examine a treatment group comprised of fruits and nuts, root vegetables, vine and stalk vegetables, and leafy vegetables. Combining all four of these product categories into a single treatment group produces no statistically significant estimates of the effect of the Final Juice Rule. When estimating the effect of the Final Juice Rule on each of these four treatment groups in isolation, we observe statistically significant results only for the fruit and nut product category.

[11] Performing the analysis using fruit and nut products as the treated group, but omitting root vegetables, vine and stalk vegetables, and leafy vegetables from the control group, and thus the analysis itself, does not alter our conclusions.

[12] The Final Juice Rule had a staggered compliance period for small and very small producers in 2003 and 2004, respectively. Thus, it is possible that some shifts in the industry continued to occur after our examined cutoff.

[13] For example, it is possible that fruits not intended for juice processing pass through the same plants, are handled by the same workers, or are transported by means which have improved sanitary practices due to HACCP training for the compliance with the Final Juice Rule.

[14] Other measures besides the Final Juice Rule might have had an impact on the number of foodborne illnesses associated with juice-bearing products during the time period considered in our analysis (1998–2008). For example, in the same year in which it introduced a proposed version of the Final Juice Rule (1998), the FDA issued a Final Labeling Rule, effective in the same year, requiring a warning statement on juice products not processed to prevent, reduce, or eliminate potential pathogens. This Final Labeling Rule initially covered all packaged juice products. After the Final Juice Rule went into effect, the Final Labeling Rule no longer applied to juice products covered under the Final Juice Rule. Because our data begin in 1998, we are unable to control for the Final Labeling Rule in our analysis. To the best of our knowledge, but for the Final Labeling Rule, there was no regulation per se of the juice industry prior to the Final Juice Rule, although there was (and continues to be) an inspection system in place – juice processors, similar to other food processors, were subject to periodic, unannounced, mandatory inspections by the FDA. Such inspections were based, at least in part, on Current Good Manufacturing Practice (CGMP) regulations, which provide guidance to food manufacturers on how to reduce insanitary manufacturing practices and protect against food contamination. Additional measures which might have had an impact on the number of foodborne illnesses associated with juice-bearing products during the time period used in our analysis include private food safety standards such as GLOBALG.A.P., an independent certification system for Good Agricultural Practice (G.A.P.) which began in Europe in 1997 (GLOBALG.A.P., 2016). However, we are unable to control for GLOBALG.A.P. in our analysis because our data begin in 1998. It could also be that changes in Maximum Residue Limits (MRLs), which are maximum acceptable levels of pesticides and veterinary drugs in food and agricultural products (United States Department of Agriculture Foreign Agricultural Service, 2016), during the time period studied in our analysis may have impacted the number of foodborne illnesses associated with juice-bearing products. However, our data set is not granular enough to allow us to control for MRLs, which can vary by fruit/vegetable, by pesticide/drug, and by the country in which the fruit/vegetable is sold. We are unaware of any other relevant food safety measures which we are able to control for during the 1998–2008 time period.

Table 2
Summary statistics for pathogen indicators.

Pathogen	Full sample period				Pre-rule		Post-rule	
	Mean	S. D.	Min.	Max.	Mean	S. D.	Mean	S. D.
Anisakis	0.01	0.07	0.00	1.00	0.01	0.12	0.00	0.00
Bacillus cereus	0.74	0.44	0.00	1.00	0.82	0.38	0.70	0.46
Brucella	0.02	0.15	0.00	1.00	0.01	0.12	0.03	0.16
Campylobacter	0.49	0.50	0.00	1.00	0.37	0.49	0.55	0.50
Clostridium botulinum	0.21	0.41	0.00	1.00	0.15	0.36	0.25	0.44
Clostridium perfringens	0.78	0.42	0.00	1.00	0.79	0.41	0.76	0.43
Cryptosporidium	0.04	0.20	0.00	1.00	0.07	0.26	0.03	0.16
Cyclospora	0.13	0.34	0.00	1.00	0.04	0.21	0.18	0.39
E. coli	0.65	0.48	0.00	1.00	0.68	0.47	0.64	0.48
Giardia	0.09	0.28	0.00	1.00	0.01	0.12	0.13	0.33
Hepatitis A	0.26	0.44	0.00	1.00	0.40	0.49	0.18	0.38
Listeria monocytogenes	0.14	0.35	0.00	1.00	0.13	0.34	0.15	0.36
Marine Biotoxins	0.28	0.45	0.00	1.00	0.37	0.49	0.24	0.43
Mycotoxins	0.06	0.25	0.00	1.00	0.03	0.17	0.08	0.28
Other Chemicals	0.58	0.50	0.00	1.00	0.59	0.50	0.57	0.50
Rotavirus	0.10	0.30	0.00	1.00	0.12	0.32	0.09	0.29
Salmonella	0.93	0.26	0.00	1.00	0.96	0.21	0.92	0.28
Sapovirus	0.01	0.10	0.00	1.00	0.00	0.00	0.02	0.13
Shigella	0.50	0.50	0.00	1.00	0.60	0.49	0.45	0.50
Staphylococcus	0.81	0.39	0.00	1.00	0.84	0.37	0.80	0.40
Trichinella	0.06	0.25	0.00	1.00	0.07	0.26	0.06	0.24
Vibrio	0.28	0.45	0.00	1.00	0.40	0.49	0.22	0.41
Yersinia	0.05	0.21	0.00	1.00	0.09	0.29	0.03	0.16

Notes: Full sample period summary statistics contain 187 observations; 68 for the pre-rule period (1998–2001); and 119 for the post-rule period (2002–2008). 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.

size of the United States food or agricultural market (United States Department of Agriculture Economic Research Service, 2014a).

Finally, $\varepsilon_{i,t}$ is a random error term. Our primary interest is in α_1, the difference-in-differences estimate of the effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products. Although our data are not strictly count data, we perform an additional robustness check of estimating the effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products using a Poisson regression model. Presented in Appendix Table A.2, the results suggest effects similar to those presented in our main analysis.

4. Results

Table 3 presents our estimates of the effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products (Appendix Table A.1 contains a more detailed version of these results). Model 1, which controls for product and pathogen fixed effects as well as price and volume controls, indicates that the Final Juice Rule reduced the number of foodborne illnesses associated with juice-bearing products by approximately 475 per year. Model 2, which adds national controls, reveals similar results. The national controls are similar to year fixed effects in that they control for factors that vary over time, but not across product categories. Model 3 includes year fixed effects and produces similar, albeit somewhat smaller, results.[15]

As a falsification test, we perform these analyses on each of the other product categories individually, defining each time a different product category as the treatment group. Only the eggs product category produces significant estimates across all three models and most produce no significant results at all. The effect on eggs can be explained by similarly timed regulations which affected the shell egg market (see Minor and Parrett (2016)).[16]

Table 3
The effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products.

	(1)	(2)	(3)
Final Juice Rule ∗ Juice-bearing products	−475.21*	−507.86**	−461.71*
	(254.06)	(242.25)	(265.37)
Final Juice Rule	−113.45	13.61	−142.65
	(79.93)	(114.78)	(193.67)
Juice-bearing products	−895.40	−1293.85	−874.71
	(1364.92)	(1409.71)	(1354.12)
Observations	187	187	187
$\mathbf{R^2}$	0.77	0.79	0.80
Controls			
Price, volume, product, & pathogen controls	X	X	X
National controls	–	X	–
Year fixed effects	–	–	X

Notes: The dependent variable in all three models is the total number of foodborne illnesses. Juice-bearing products refer to fruit and nut products. Robust standard errors in parentheses.
* Denotes 10% significance level (two-tailed).
** Denotes 5% significance level (two-tailed).

5. Discussion

We find evidence that the FDA's Final Juice Rule reduced the number of foodborne illnesses associated with juice-bearing

[15] We are unable to include both the national controls and year fixed effects at the same time because both are constant across product categories in a given year (perfect collinearity). The smaller magnitudes estimated in Model 3 likely indicate that the year fixed effects are able to capture more variation in illnesses than the national controls alone.

[16] Minor and Parrett (2016) find that the FDA's proposed rule titled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production", published in 2004, decreased the number of *Salmonella* illnesses associated with the consumption of shell eggs.

products by between 462 and 508 annually. Although we are not able to point to a specific mechanism in this study, it is likely that these effects came about by some combination of safer production practices and less safe producers or products exiting the market.[17] For example, anecdotal evidence suggests that in response to the Final Juice Rule, some manufacturers of unpasteurized juice and cider products ceased production in lieu of implementing HACCP. Thus, some of the observed reduction in foodborne illnesses, while attributable to the Final Juice Rule, may not be directly attributable to HACCP. We find no evidence that the Final Juice Rule reduced illnesses across other food commodities or that juice commodities are estimated to be significantly different from other commodities with respect to foodborne illnesses.

Using the above estimates, we reevaluate the benefits of the Final Juice Rule originally estimated by the FDA in the FRIA. To do this, we use our estimated average annual reduction in foodborne illnesses of 485 (= [462 + 508]/2) and a weighted average multiplier of 36, obtained using the pathogen-specific multipliers reported in Scallan et al. (2011) and the relative frequency of foodborne illnesses by pathogen for the fruits and nuts juice-bearing product category,[18] the product of which yields 17,460 (= 485 $\times$ 36) foodborne illnesses prevented annually by the Final Juice Rule. Combining this with weighted average low and high cost of foodborne illness estimates of between $3369 and $4714 per illness, obtained using costs of foodborne illness reported in Minor et al. (2015) and a similar weighting scheme as above, produces an annual reevaluated benefit of between $59 million (=17,460 $\times$ $3369) and $82 million (=17,460 $\times$ $4714) (2014$).

The FDA's benefits estimates are based on historical (1992–2000) juice outbreak data. Using these data, the FDA calculated the average number of reported juice-related illnesses per year for each of the four pathogens present in the dataset. The illness calculations were then adjusted to account for foodborne illness underreporting and underdiagnosis, as well as to subtract those cases of foodborne illness that the FDA believed the Final Juice Rule would not be able to prevent. The resulting illness calculations represent the FDA's estimate of the number of juice-related illnesses per year that the Final Juice Rule would reduce. Using the number of quality adjusted life days (QALDs) lost due to each of the four foodborne illness types, valued at roughly $842 per QALD (2014$) by the FDA, as well as the medical costs associated with each foodborne illness type, the FDA valued its estimate of the number of juice-related illnesses per year that the Final Juice Rule would reduce at approximately $202 million annually (2014$).

Comparing and contrasting the two benefits estimates, the first observation is that both exceed the annual $38 million (2014$) cost to industry estimated by the FDA in the FRIA.[19] The second observation is that our estimate of benefits is much smaller than the FDA's. More precisely, the benefits associated with the Final Juice Rule estimated by us are between 29 percent and 41 percent of those which were estimated by the FDA in the FRIA. However, in estimating the benefits of the Final Juice Rule, we had the luxury of hindsight (data collected since the publication of the Final Juice Rule). In contrast, because the regulation promulgation process requires that the agency issuing the rulemaking estimate the costs and benefits of the rule before the rule is published, the FDA had to rely on foresight (estimates of the impact of the rule based on data collected prior to the publication of the Final Juice Rule).

6. Conclusion

Using 1998–2008 data collected by the CDC and compiled by Painter et al. (2013) on foodborne illnesses and outbreaks, we examined using a difference-in-differences approach the effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products. This paper fills a gap in the food safety standards literature by being the first to our knowledge to directly examine consumer health effects using a rigorous identification strategy. Vojdani et al. (2008) directly examined consumer health effects of the Final Juice Rule, but lack a convincing identification strategy–they just looked at the number of juice-related outbreaks of foodborne illness pre- and post-implementation of the Final Juice Rule. Related studies have focused either on indirect consumer health effects, vis-a-vis their examination of the effect of food safety standards on the microbiological quality of foods (e.g., Amoa-Awua et al., 2007; Cenci-Goga et al., 2005; Hong et al., 2008; Nada et al., 2012; Soriano et al., 2002; Wang et al., 2010), or on producer health effects (e.g., Asfaw et al., 2010; Okello and Swinton, 2010). Recent food safety standards papers which have appeared in *Food Policy* have focused not on health effects but rather on foreign trade effects (e.g., Ferro et al., 2015; Herzfeld et al., 2011; Jongwanich, 2009; Shepherd and Wilson, 2013).

We find that the Final Juice Rule led to a reduction in the number of foodborne illnesses associated with juice-bearing products of between 462 and 508 per year, resulting in a cost savings of between $59 million and $82 million per year (2014$). From a policy perspective, that the annual cost savings associated with the Final Juice Rule compares favorably to the rule's estimated annual cost of roughly $38 million (2014$) lends credence to the Final Juice Rule, and perhaps more generally to the use of HACCP elsewhere.

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

[17] Additionally, estimates of the average size of an outbreak associated with juice-bearing products suggest that the size of an outbreak was reduced by approximately 19 illnesses per outbreak following the implementation of the Final Juice Rule (estimates available upon request). This indicates that the drop in foodborne illnesses we estimate may be due to limiting the size of a standard outbreak associated with juice-bearing products rather than a simple reduction in the number of foodborne outbreaks associated with juice-bearing products. Conversely, this could indicate that juice-bearing product outbreaks were larger in scope on average than other fruit and nut related outbreaks and removing those measurably lowered the average illnesses per outbreak.

[18] The data used in this paper are based on state and local health department reports of foodborne illnesses to the CDC. However, due to underdiagnosis (many people are never officially diagnosed with a foodborne illness) and underreporting (some foodborne illnesses never get reported to public health authorities), such reports typically capture just a fraction of the actual number of foodborne illnesses. The pathogen-specific multipliers estimated by Scallan et al. (2011) are used to correct for this. Here, we use a weighted average multiplier which spans the pathogens we observe in our data that cause juice-bearing product related foodborne illnesses, and which weights each pathogen-specific multiplier included in the weighted average calculation by the pathogen's relative contribution to the total number of juice-bearing product related foodborne illnesses.

[19] Consistent with the parameters used by the FDA in the FRIA, the $38 million in annual costs were computed by annualizing over an infinite time horizon and at a 7% discount rate the FDA's present value cost estimate of $535 million (2014$). The FDA estimated the total cost of the Final Juice Rule by summing up over all of the requirements mandated by the Final Juice Rule the cost of each requirement, given by $Cost_i$ = Per-Plant $Cost_i$ x # Affected $Plants_i$.

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 number of treated observations (juice-bearing product observations), 11 in total, is small relative to the total number of observations (187). Third, 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. Fourth, our estimates examine a change after the effective date of the Final Juice Rule for juice producers. It is possible, though, that there may have been changes in the industry prior to the effective date of the Final Juice Rule, as the proposed version of the Final Juice Rule was published in 1998, the first year of our observed data. However, because we are unable to make a pre- and post-period comparison of the proposed version of the Final Juice Rule, we are not able to formally test if there was a change in the industry due to the publication of the proposed version of the Final Juice Rule, prior to the implementation of the requirements of the Final Juice Rule. If there was some change in the industry due to the publication of the proposed version of the Final Juice Rule, our estimates may represent an underestimation of the full effect that Juice HACCP had on the industry.[20] Fifth, as discussed in more detail in footnote 14, there are other measures for which we are unable to control but which might have had an impact on the number of foodborne illnesses associated with juice-bearing products during the time period considered in our analysis. Hence, our estimate of the effect of the Final Juice Rule on the number of juice-related foodborne illnesses and, in turn, our estimate of the reevaluated benefits of the Final Juice Rule, could be biased upwards, but likely only slightly, as these measures are arguably smaller in scope than the Final Juice Rule. Finally, our analysis looks at the effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products, not juice products per se, as the Painter et al. (2013) data do not contain a juice per se product category. Future research should examine the effect of the Final Juice Rule on the number of foodborne illnesses associated with juice products per se using the raw NORS data; however, cleaning and compiling the raw NORS data for use in this exercise will be no easy feat. Additionally, it would be interesting to examine what, if any, international effects were a result of the Final Juice Rule. International data on foodborne illnesses from comparable countries such as Canada or the United Kingdom could provide additional control groups from which the effects of the Final Juice Rule in the U.S. could be measured. However, given the currently utilized data set and the relative inconsistency of international foodborne illness data, these analyses are currently outside the scope of this analysis.

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[20] Fig. 1 may indicate that there was, in fact, some downward movement in foodborne illnesses associated with juice-bearing products prior to the effective date of the Final Juice Rule.

Appendix A

Table A.1
The effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products – price and volume, national, and year fixed effect results.

	(1)	(2)	(3)
Final Juice Rule ∗ Juice-bearing products	−475.21*	−507.86**	−461.71*
	(254.06)	(242.25)	(265.37)
Final Juice Rule	−113.45	13.61	−142.65
	(79.93)	(114.78)	(193.67)
Juice-bearing products	−895.40	−1293.85	−874.71
	(1364.92)	(1409.71)	(1354.12)
Price and volume controls			
Consumer price index	−290.63*	−140.66	−193.30
	(164.94)	(217.70)	(205.48)
Producer price index	−1.09	−1.20	−0.83
	(1.24)	(1.20)	(1.18)
Consumer expenditures	0.16	−0.41	−2.09
	(1.68)	(1.87)	(2.10)
Food available	0.01	0.02	0.01
	(0.02)	(0.02)	(0.02)
Import volume	0.04	0.05**	0.05*
	(0.03)	(0.03)	(0.03)
Import value	0.04	0.07*	0.08*
	(0.03)	(0.04)	(0.04)
National controls			
Temperature		−173.84**	
		(75.40)	
Precipitation		102.07*	
		(52.27)	
Palmer Z drought index		−256.30*	
		(135.14)	
Population		−16.32**	
		(8.05)	
# Farms		−0.00	
		(0.00)	
Year fixed effects			
1999			−100.28
			(110.75)
2000			38.59
			(119.87)
2001			−51.60
			(112.63)
2003			140.72
			(164.31)
2004			−74.57
			(131.18)
2005			74.61
			(142.33)
2006			−263.36**
			(126.31)
2007			5.08
			(110.73)
2008			−237.94**
			(103.32)
Constant	979.21	13468.09**	1147.11*
	(645.20)	(5602.51)	(682.88)
Observations	187	187	187
R^2	0.77	0.79	0.80
Controls			
Price, volume, product, & pathogen controls	X	X	X
National controls	–	X	–
Year fixed effects	–	–	X

Notes: Also included, but not presented are product and pathogen fixed effects. Full estimates are available upon request. Juice-bearing products refer to fruit and nut products. Robust standard errors in parentheses.
* Denotes 10% significance level (two-tailed).
** Denotes 5% significance level (two-tailed).

Table A.2
The effect of the Final Juice Rule on the number of foodborne illnesses associated with juice-bearing products – Poisson regression results.

	(1)	(2)
Final Juice Rule ∗ Juice-bearing products	−0.587***	−0.592***
	(0.217)	(0.204)
Final Juice Rule	−0.151	0.018
	(0.102)	(0.131)
Juice-bearing products	−1.986	−2.980*
	(1.652)	(1.737)
Observations	187	187
Pseudo R^2	0.830	0.846
Controls		
Price, volume, product, & pathogen controls	X	X
National controls	–	X

Notes: Coefficients should be interpreted as percent changes. Juice-bearing products refer to fruit and nut products. Robust standard errors in parentheses.
* Denotes 10% significance level (two-tailed).
*** Denotes 1% significance level (two-tailed).

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