Food Policy 68 (2017) 206–213

Contents lists available at ScienceDirect

Food Policy

journal homepage: www.elsevier.com/locate/foodpol

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

Travis Minor [a], Matt Parrett [b,*]

[a] US Department of Agriculture, Economic Research Service, 1400 Independence Avenue SW, Washington, DC 20250, United States
[b] Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, United States

ARTICLE INFO

Article history:
Received 9 November 2015
Received in revised form 3 February 2017
Accepted 25 February 2017
Available online 8 March 2017

Keywords:
Foodborne illness
Juice
Regulation
HACCP

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.

Published by Elsevier Ltd.

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

☆ The views expressed here are those of the authors, and may not be attributed to the Economic Research Service, the U.S. Department of Agriculture or the Food and Drug Administration.

* Corresponding author.
E-mail addresses: Travis.Minor@ers.usda.gov (T. Minor), mbparrett@gmail.com (M. Parrett).

[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.

http://dx.doi.org/10.1016/j.foodpol.2017.02.008
0306-9192/Published by Elsevier Ltd.

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.