What Drives Food Import Refusals?

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Even before the recent discovery of salmonella in peanuts or melamine-tainted infant formula from China, food safety had become a recurring theme in the news. In response the U.S. Food and Drug Administration (FDA) proposed to revamp its international and domestic screening system, and is the subject of a new food safety bill (Martin 2008; Harris 2009). However, increased regulatory burdens at the border can hinder trade. This article explores the causes and implications of U.S. import refusals.

Because the FDA has limited resources, they have to carefully choose what to inspect. This resource constraint might lead inspections to be path dependent, as inspectors target products and firms that have had problems in the past. While this approach may account for some higher risk products, it may leave others under-inspected. For example, new exporters may go through a learning phase, where their ability to meet safety regulations develops over time. Second, as is often claimed by countries whose imports have been targeted with an import refusal, food inspection decisions might be influenced by domestic policy concerns. At a minimum, FDA inspections have to account for changes in food regulation, which can occur for political reasons.

In this article we consider factors associated with import refusals. Little literature on import food inspections exists, in large part because of the lack of data (notable exceptions include: Allshouse et al. 2003; Anders and Caswell 2007; Brooks, Buzby, and Regmi 2008; Buzby, Unnevehr, and Roberts 2008; and Calvin 2003). Data on import refusals are rare, and since inspections are neither observed nor random, these refusal data suffer from selection bias (Buzby, Unnevehr, and Roberts 2008). We address this
potential bias by controlling for import alerts, which help to allocate FDA resources. We have two further contributions. We consider the effect of exporter learning on import refusals and we ask whether domestic political concerns matter.

**Background on Food Trade and Inspections**

To export a food product to the United States, an importer first needs to submit information identifying the product, its quantity, country of origin, shipper, manufacturer and importer. After reviewing the electronic documents, the FDA agent decides whether to examine the product, hold it for further information, or release it into the United States (Humphrey 2003; Buzby, Unnevehr, and Roberts 2008). The FDA agent can conduct a sensory evaluation for rodent or insect filth, label compliance or evidence that the product may be adulterated. If the agent expects the presence of toxins or additives, she/he can request a further lab test (Buzby, Unnevehr, and Roberts 2008).

*Import Refusals*

If the product is refused entry, the importer is informed, and may provide further information supporting the product’s compliance or a plan to bring the product into compliance, such as relabeling. Unless the product is shown to meet U.S. guidelines, it must be re-exported or destroyed within 90 days (Humphrey 2003).

Formally, imported products are required to meet the same standards as domestic goods: imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions (FDA 2009). That said, compared with domestic products, imports are deemed to be in violation of the Food, Drug and Cosmetics Act (FDCA) if they merely
“appear” to be adulterated or misbranded, without a clear definition of “appearance” (Humphrey 2003). This additional regulatory stringency may exist because the FDA does not have the right to inspect foreign processing plants, and therefore only has information of the final product to determine product safety. By contrast the Department of Agriculture’s Food Safety and Inspection Service (FSIS), which has jurisdiction over meat, poultry, egg and newly, catfish imports, only allows imports from those countries with food safety systems that it deems to be equivalent to the U.S. system. The FDA, which regulates all other foods, lacks this authority. Only 1 to 2 percent of the food imported under FDA jurisdiction is visually inspected, and one tenth of that is sampled (Barrionuevo 2007).

Import Alerts

Because the FDA has the resources to only examine a small percentage of food imports, it makes use of general guidelines or “alerts” to guide those inspections. Alerts may be issued if the FDA determines that a product appears to violate the agency’s rules and regulations and are primarily directed at specific exporting firms, but can be national or worldwide when the problem appears widespread. Most alerts state that future shipments of the product will be “detained without physical examination” unless the importer demonstrates that the product is in compliance with the FDCA, essentially shifting the burden of proof onto the importer (Humphrey 2003). FDA field staff have broad discretion over what constitutes a reason for an alert. In April 2009, existing alerts were triggered by previous FDA refusals, information from other countries, and disease outbreaks in the United States.
It is striking how rarely alerts are changed. Three-quarters of the alerts in place in 2009 have been in place longer than 10 years, and more than one quarter was generated 20 years ago. Many of the cancelled alerts were wrapped into broader current alerts.

Hypotheses

We distinguish among three different types of factors that could trigger import refusals. The first set of factors relates to product-specific characteristics associated with greater risk of foodborne diseases, such as the rate of decomposition. The second set of variables is specific to the exporter. The third set of factors is related to demand for trade protection within the United States.

Hypothesis 1: There is a learning curve in import quality.

As firms in a country gain more experience in exporting a particular product, we expect them to be better able to comply with regulations that govern imports. When a country first starts to export a new product and/or starts exporting to a new country, we predict that a learning period of trial and error will take place. Hence, we test whether countries with greater experience in food trade with the United States experience fewer refusals.

Hypothesis 2: Import refusals are subject to political pressure.

Following other literature exploring the link between political pressure and trade protection (for example Goldberg and Maggi 1999; Lopez and Matschke 2006), we expect to observe a greater number of import refusals in industries facing increasing import competition and/or exerting more political pressure.
Methodology and Data

Consider an FDA employee deciding whether to detain a product. Her time is constrained, so she wants to ensure that she chooses the inspection frequency and depth to minimize the probability of a non-compliant food entering the United States. The inspector has some information about the risk of a product, which can come in the form of guidance from a pre-existing alert, information from other countries’ inspections, or past refusals. Thus, refusals are likely a function of the probability of an unsafe import where the probability of an unsafe import at any point in time can be thought of as the risk of adulteration of any one product shipment multiplied by the quantity of imports of that product.

As noted above, import inspections and thus refusals may be path dependent. On one hand, past rejections may increase import inspections while importer experience may decrease rejections. There may also be political or economic pressure for intensive import inspections. Thus, we model the probability of an import refusal as follows:

\[ P(\text{refusal}_{hkt}) = \text{risk}_{hkt} \cdot \text{volume}_{hkt} + \text{experience}_{hkt} + D(\text{trade protection})_{hkt} \]

where \( h \) is product, \( k \) is country and \( t \) is time. \textit{Risk} represents the specific risk associated with the product, \textit{volume} denotes the volume shipped to the United States, \textit{experience} corresponds to the exporter’s characteristics, and \( D(\text{trade protection}) \) is domestic demand for protection.

We want to disentangle those factors associated with true risk of a harmful or otherwise non-conforming food product entering the United States from domestic concerns and path dependence over and above what is justified by risk. We first consider
the probability of a refusal as a function of product and exporter characteristics that may be associated with higher risk, and trade volume. We then consider factors associated with U.S. economic interests and domestic political pressure.

To identify country-product pairs that might be at higher risk of contagion, we consider whether the product-country pair has recently been a target of a refusal by the European Union (EU). Many products and countries appear in both U.S. and EU import refusals, and presumably if another country finds a product in violation, the FDA would see this as cause for increased vigilance. This variable is denoted as \( EU_{refusal} \) below in equation 2. Certain product characteristics might also make a product more susceptible to contamination. First, we create a variable that identifies whether a product is perishable denoted as \( perish \). Similarly, we include products that are \( processed \). Second, we use the EU refusal data to create a variable capturing high-risk products, summing refusals by product regardless of exporter or month (\( \sum_{t=1}^{T} \sum_{k=1}^{K} EU_{refusal} \)). Third, we control for high-risk product categories, specifically seafood and meat (\( seafood, meat \)).

Country characteristics may also increase risk. Lower-income countries might pose a higher risk of exporting substandard products (\( GDP \)). Assuming that new exporters may have more difficulty meeting U.S. import standards, we create a variable indicating whether the country first exports the product to the United States after January 1998 (\( newX \)). We control for possible current alerts involving a new exporter by
including an interaction term (\(palert_{ht, newX_{ht}}\)). Countries where corruption is widespread may constitute a higher risk as well (\(corrupt_{kt}\)).

To capture learning, we control for the past value of all food products exported by that country to the United States (\(\sum_{h=1}^{H} \sum_{t=1}^{t-1} lval_{ht, t-1}\)). We also include the number of years the country has been a member of the World Trade Organization (\(WTO_{kt}\)). Firms operating in English-speaking countries might find it easier meeting English U.S. requirements (\(English_{kt}\)). Similarly, firms in bilateral or regional trade agreements with the United States may have invested more in processes and knowledge to meet U.S. import requirements (\(TA_{kt}\)).

We also control for trade volume, knowing that more trade will likely result in more violations (\(lq_{ht, t-1}\)). Next, we control for alerts. Because we only observe the alerts that are (a) either still in place in 2009, or (b), past cases explicitly referenced in the current alerts, we need to control for the unobserved past alerts. Because the alerts are numbered, we know the number of alerts issued and then withdrawn by product category. We therefore include the probability of an alert plus the existing alerts (\(palert_{ht}\)).

Last, we consider whether U.S. domestic concerns influence FDA border restrictions. We include lagged monthly lobby expenditures by U.S. industry (\(lobby_{ht, t-1}\)). Because the volume of imports may be a cause of concern for the domestic industry, we include an interaction term to differentiate the effect of lobbying contributions depending on total world imports by product (\(lobby_{ht, t-1} \cdot lworlqty_{ht, t-1}\)). We also control for total past world imports to the U.S. by product (\(lworlqty_{ht, t-1}\)). To capture pressure for trade
protection, we consider the percentage change in price of imports (**\(\% \Delta p_{ht-1}\)**) assuming that a decrease in import price may signal increased import competition. Changes in employment by U.S. industry could also reflect domestic concerns for trade protection (**\(\Delta employment_{ht}\)**). As direct evidence for demand for protection from imports, we also include a dummy variable equal to one if an anti-dumping case was filed against that product and country in the previous year (**\(AD_{hkr-1}\)**). We also include a time trend and time trend squared. The regression is given in equation 2:

\[
\text{Refusals}_{hkt} = \alpha + \beta_p \text{palert}_{hkt} + \beta_{EU} \text{EUrefusal}_{hkt-1} + \beta_{EU} \sum_{r=1}^{H} \sum_{h=1}^{H} \text{EUrefusal}_{hkt-1} + \\
+ \beta_p \text{perish}_{ht} + \beta_{TA} \text{TA}_{hkt} + \beta_d \text{English}_{hkt} + \beta_{WTO} \text{WTO}_{ht} + \beta_t \text{corrupt}_{ht} + \\
+ \beta_g \text{GDP}_{kt} + \beta_1 \sum_{h=1}^{H} \sum_{t=0}^{T} \text{lval}_{hkt-1} + \beta_m \text{newX}_{hkt} + \beta_{aux} \text{palert}_{hkt} - \text{newX}_{hkt} + \\
+ \beta_l \text{lob}_{hkt-1} + \beta_1 \text{employment}_{ht} + \beta_{wq} \text{lworldq}_{ht-1} + \beta_{lob} \text{lobby}_{ht-1} + \\
+ \beta_{lobwq} \text{lobby}_{ht-1} - \text{lworldq}_{ht-1} + \beta_{AD} \text{AD}_{hkr-1} + \beta_p \% \Delta p_{hkr-1} + \\
+ \beta_{sf} \text{seafood}_{h} + \beta_{m} \text{meat}_{h} + \beta_p \text{process}_{h} + \beta_t \text{time}_{h} + \beta_t \text{time2}_{t} + \nu_{hkt}
\]

(2)

One might be concerned about simultaneity of alerts and refusals, since an import refusal can trigger an alert. Given that our data on refusals is relatively recent (from 1998-2004), and most of our alerts pre-date these data, we model alerts as pre-existing.\(^{5}\)

When we studied the events that triggered an alert, only 14 of 124 separate alerts were triggered by FDA inspections that occurred after January 1, 1998. Of the alerts issued after 1998, the majority were triggered either by an event prior to 1998, a domestic disease outbreak or a finding by others, for example the New York Board of Health. We remove these 14 potentially endogenous alerts from our data when considering refusals.\(^{6}\)

As a robustness check, we also run the regression for only those refusal cases where pre-
existing alerts exist. Furthermore, we add past refusals as explanatory variable without changing our previous results.

Data on U.S. refusals are provided by our collaborators at the Economic Research Service, tabulated by month, FDA product and country, for a total of 68,000 refusals from 1998 to 2004. Data on FDA import alerts are obtained from the FDA website. Although the alert may have initially been directed at one country, we also include the later countries and products to which it was expanded, when it was expanded. We restrict ourselves to alerts on food products (FDA codes 02 through 45) and do not include those food products under miscellaneous (FDA code 99). Because we only observe current alerts, when using alerts as an explanatory variable, we include the probability that an alert was in place and later removed by product category. Notably, for many products no alert was removed, and the only two broad categories for which more than 10 alerts were withdrawn are seafood and vegetables. In total we observe 124 cases containing 1,920 country-product pairs. EU refusal data was obtained by the European Commission, and contains the number of refusals by country, product, month, reason, and refusal type from January 1998 through August 2008, for a total of 14,102 refusals. As with the above data, we match the data to FDA 2-digit codes from the product description.

Our lobby data come from the Center for Responsive Politics (2009). We classify annual lobby expenditure by industry code of the spender, and then match these data to monthly trade data at the FDA 2-digit level (Foreign Agricultural Service 2009) and employment data by industry (Bureau of Labor Statistics 2009). We restrict ourselves to country-product pairs that export at least some amount to the United States between 1998
and 2008. We include country characteristics on income from the World Bank World Development Indicators (2009), trade characteristics from the World Trade Organization (2009), official language from the CIA World Factbook (2009), and freedom from corruption from the Heritage Foundation (2009). Last, data for U.S. antidumping investigations for 1991-2004 are compiled using the information provided by the U.S. International Trade Commission (2009) and the U.S. International Trade Administration (2009). All data are merged by product code, country, and month.

**Results**

Since our data indicate overdispersion, we use a panel-specific negative binomial regression with random effects to estimate the number of refusals by country, product and month, giving us 302,385 observations. Full results are presented in table 1. As anticipated, we observe that a larger number of alerts is associated with a larger number of refusals for that country-product pair. Second, lagged quantity traded is highly correlated with the number of refusals. To address potential concerns of endogeneity in the lagged quantity traded, we also instrument for it using distance and the exchange rate, and find our results unchanged.

The evidence conflicts with our first hypothesis that new exporters see more export refusals. If a country is a new exporter of a certain product, it faces fewer import refusals. A potential explanation is that new exporters tend to rely more on customs brokers that have a vast experience. Similarly, cumulative sales of all food products to the United States are strongly positively correlated with the number of refusals in any one food category, even after controlling for the quantity shipped of the specific product.
Add the fact that English-speaking countries and exporters with higher GDP are also more likely to generate refusals, we appear to be observing a form of familiarity breeding contempt. One exception is that the longer a country is in the WTO, the fewer the number of refusals. These results may imply that, like alerts, inspections are targeted at past violators more than new or small exporters.

Considering our second hypothesis, we find some evidence that domestic interests do influence the number of refusals. Although lagged lobby expenditure seems to have a little effect on refusals at the average level of imports, we observe more refusals when we interact lobby expenditure with total world imports. Thus, for those sectors and times with a larger than average quantity of imports, we see lobbying increasing the number of refusals. Furthermore, when we restricted the sample to those products the U.S. produces in abundance (excluding seafood, spices, coffee and tea), we see the overall effect of lobbying become insignificant, and only the positive interaction between lobbying and world imports. Second, we see that a decrease in employment by U.S. industry is positively correlated with refusals and, although not strongly significant, a decrease in import price also leads to more refusals. Both these results provide evidence in support of our second hypothesis. Notably, we also observe that an antidumping case in the previous year was highly correlated with a larger number of import refusals for that country-product pair.

Corruption in the exporting country increases the number of refusals. Further, we observe that if the Europeans find a problem with the product, the United States is more likely to reject it as well, especially when we aggregate to the product category.
We also estimate the number of refusals for those country-product pairs where a known alert is in place, giving us 115,265 observations (see table 1). The results are very similar to those where we control for alerts as an explanatory variable. While the significance level of some coefficients increases, the signs remain largely unchanged.

Conclusions
The FDA has the difficult task of ensuring the safety of the U.S. food supply with limited resources and without unduly hindering trade. In this article, we attempt to discern how the FDA is currently targeting inspections and ask what factors are associated with import refusals.

We ask whether new exporters are subject to more refusals. If anything, we find the converse. Those countries newly exporting a product are subject to fewer refusals, and countries with more experience exporting all agricultural products to the United States are subject to more import refusals. Given we control for import quantity, this result may indicate that, as we observe with import alerts, inspections are targeted at countries and products that have previously been identified as not meeting U.S. standards, while less long-standing traders may be under less scrutiny.

Second, we find that although risk factors are highly correlated with the number of import refusals, we also observe domestic political concerns playing a role. Lobbying expenditure increases the number of refusals for those sectors and times where there is a high volume of imports. Decrease in employment for a particular sector is correlated with a higher number of refusals. We also observe a higher number of refusals for those
country-product pairs recently targeted by an antidumping complaint. These results suggest that domestic interests may be influencing the direction and stringency of import food inspections.
References


Table 1. Results of Negative Binomial Regression on U.S. Import Refusals

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coeff.</th>
<th>S.E.</th>
<th>Coeff.</th>
<th>S.E.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number and probability of alert</td>
<td>0.274***</td>
<td>0.016</td>
<td>0.256***</td>
<td>0.016</td>
</tr>
<tr>
<td>Lagged EU refusals by product</td>
<td>0.692***</td>
<td>0.244</td>
<td>0.437*</td>
<td>0.264</td>
</tr>
<tr>
<td>Lagged EU refusals</td>
<td>0.623</td>
<td>0.466</td>
<td>0.835''</td>
<td>0.458</td>
</tr>
<tr>
<td>Perishable</td>
<td>0.794***</td>
<td>0.084</td>
<td>0.437***</td>
<td>0.105</td>
</tr>
<tr>
<td>Processed</td>
<td>-0.378***</td>
<td>0.048</td>
<td>-0.216***</td>
<td>0.055</td>
</tr>
<tr>
<td>Trade agreement with US</td>
<td>-0.562</td>
<td>0.513</td>
<td>-1.135*</td>
<td>0.585</td>
</tr>
<tr>
<td>English-speaking</td>
<td>0.469***</td>
<td>0.032</td>
<td>0.519***</td>
<td>0.036</td>
</tr>
<tr>
<td>Years as a member of WTO</td>
<td>-0.548***</td>
<td>0.090</td>
<td>-0.699***</td>
<td>0.099</td>
</tr>
<tr>
<td>Freedom from corruption</td>
<td>-0.146***</td>
<td>0.012</td>
<td>-0.134***</td>
<td>0.013</td>
</tr>
<tr>
<td>GDP per capita PPP</td>
<td>0.108***</td>
<td>0.025</td>
<td>0.129***</td>
<td>0.028</td>
</tr>
<tr>
<td>Lagged log value of ag exports</td>
<td>0.215***</td>
<td>0.010</td>
<td>0.182***</td>
<td>0.013</td>
</tr>
<tr>
<td>New exporter</td>
<td>-0.311***</td>
<td>0.055</td>
<td>-0.664***</td>
<td>0.092</td>
</tr>
<tr>
<td>Alerts for new exporters</td>
<td>0.187***</td>
<td>0.029</td>
<td>0.250***</td>
<td>0.035</td>
</tr>
<tr>
<td>Lagged log volume</td>
<td>0.187***</td>
<td>0.007</td>
<td>0.199***</td>
<td>0.008</td>
</tr>
<tr>
<td>Change in employment</td>
<td>-0.355***</td>
<td>0.069</td>
<td>-0.353***</td>
<td>0.071</td>
</tr>
<tr>
<td>World import quantity</td>
<td>-0.261***</td>
<td>0.017</td>
<td>-0.215***</td>
<td>0.025</td>
</tr>
<tr>
<td>Lagged lobby expenditure</td>
<td>-0.932***</td>
<td>0.299</td>
<td>-1.446***</td>
<td>0.344</td>
</tr>
<tr>
<td>Lagged lobby expenditure x import qty</td>
<td>0.707***</td>
<td>0.233</td>
<td>1.120***</td>
<td>0.268</td>
</tr>
<tr>
<td>Lagged antidumping case</td>
<td>0.746**</td>
<td>0.033</td>
<td>0.766***</td>
<td>0.037</td>
</tr>
<tr>
<td>Lagged change world price</td>
<td>-0.130</td>
<td>0.090</td>
<td>-3.833***</td>
<td>1.387</td>
</tr>
</tbody>
</table>

Number of Observations: 302,385, 115,265
Wald Chi-squared: 11,060***, 8,025***

Note: asterisks indicate levels of significance: *** = 1%, ** = 5%, * = 10%.
We study food imports valued at more than $2,500 and intended for resale.

The FDA inspects operations abroad when the firms agree. The FDA recently opened an office in China and plans other locations (Jacobs and McDonald 2008).

Storable products are coded as zero; frozen goods and produce with a longer shelf-life are coded as one; fresh fish, meat, and less durable produce are coded as 2.

Meat and seafood have distinct import protocols. The USDA handles meat and the FDA instituted a HACCP program for seafood in 1997 (Anders and Caswell, 2007).

A regression instrumenting for alerts has the same qualitative results.

Any alerts or country-product pairs included in an alert after January 1998 where the triggering event is not clearly exogenous are also removed from the sample.

The disparity between the number of U.S. and European refusals is due to the fact that unlike in the U.S., in the EU misbranding is not included in the refusal data.

A different process might drive “zero” observations. A logit specification with a binary refusal variable has the same qualitative results as those presented in table 1.