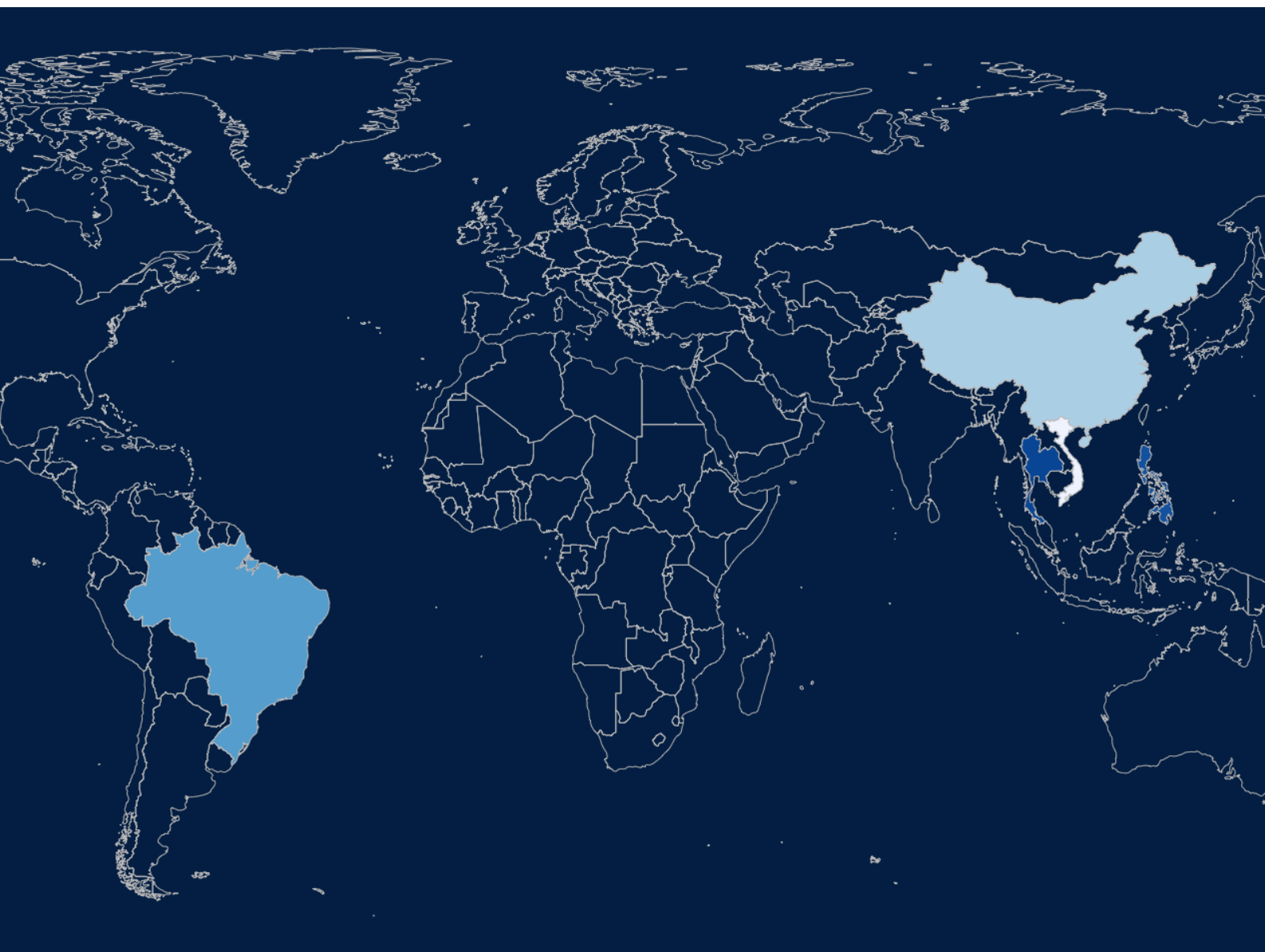


# Massive Data Institute

## **The Evaluation of Regulatory Efficiency on Catfish Imports, from FDA to USDA**

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## EXECUTIVE SUMMARY

To protect domestic catfish producers, US Congress passed laws shifting authority over catfish import regulations to the USDA, away from the FDA which traditionally regulates seafood products. Since the finalization of this transition in September 2017, the USDA has consistently refused more catfish products than the FDA, even when considering similar economic circumstances like comparable trade demand. However, while total refusals have increased under the USDA, food safety refusals have decreased, an outcome within expectations as major exporters like Vietnam, China, and Thailand gained FSIS equivalence in 2019 that deemed their internal regulations comparable to the United States. While this legislation intended to limit international imports, the obstacles implemented have been ineffective. The amount refused under USDA authority pales in comparison to the sheer amount continuously imported while FSIS equivalence has already been met.

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# Background

## Vietnamese Catfish Entered US Markets in 1994

Tra and basa fish, also known as pangasius, is a genus of catfish that have been traditionally bred by fish farmers in the Mekong Delta of Vietnam (Tu Van Binh, 2006). After the United States lifted the embargo on Vietnam in 1994, Vietnamese catfish burst onto the US market. By 2002, the US became the main export destination for Vietnam and accounted for 50% of total production (Brambilla, 2012). Vietnam catfish quickly snatched a huge market share of the catfish market, and consequently lowered the US catfish market price by 66% percent from 1997 to 2002 (National Agricultural Statistics Service, 2002).

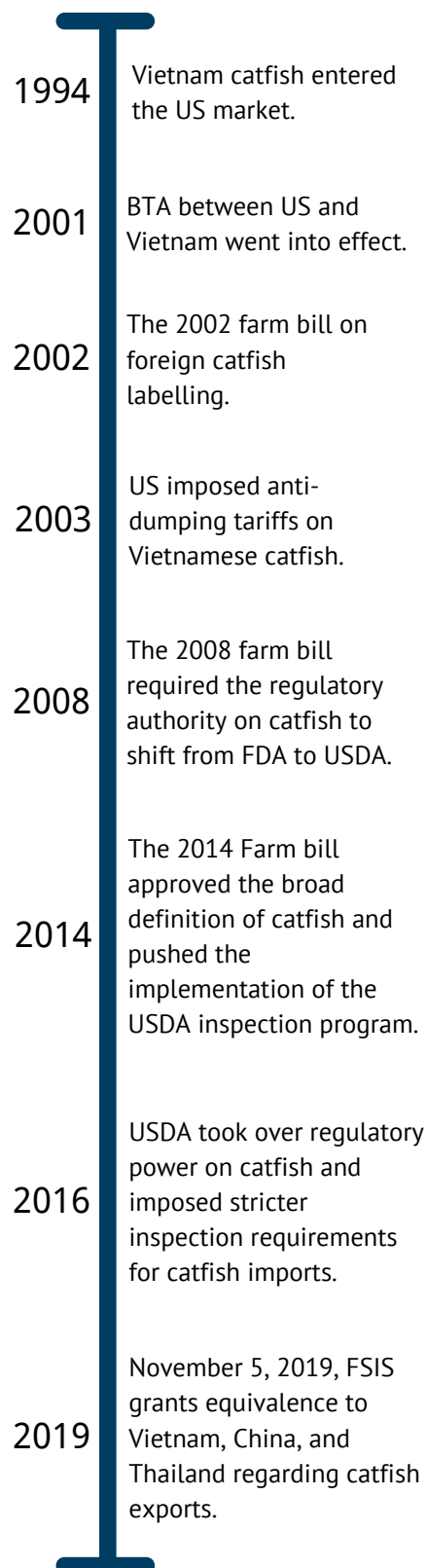
## US Catfish Farmers Fought Back

In 2002, the US Catfish Farmers' Association (CFA) and eight seafood production companies filed an application with the US International Trade Commission (ITC) to sue the Vietnamese Association of Seafood Exporter and Processors (VASEP) for dumping catfish products in the US. Despite a bilateral trade agreement (BTA) between the US and Vietnam in went into effect in 2001, in 2003, the US Department of Commerce (DOC) ruled in favor of the CFA's dumping claim and established tariffs ranging from 37% to 64% on imports of frozen catfish from Vietnam (Brambilla, 2012).

Additionally, the Farm Security and Rural Investment Act of 2002, determined that fish belonging to the family of Pangasiidae that are produced in Asia, such as tra and basa, could no longer be marketed with the label of "catfish" within the United States. This new law on labeling was intended to differentiate domestically produced catfish and obtain a relatively higher market price.

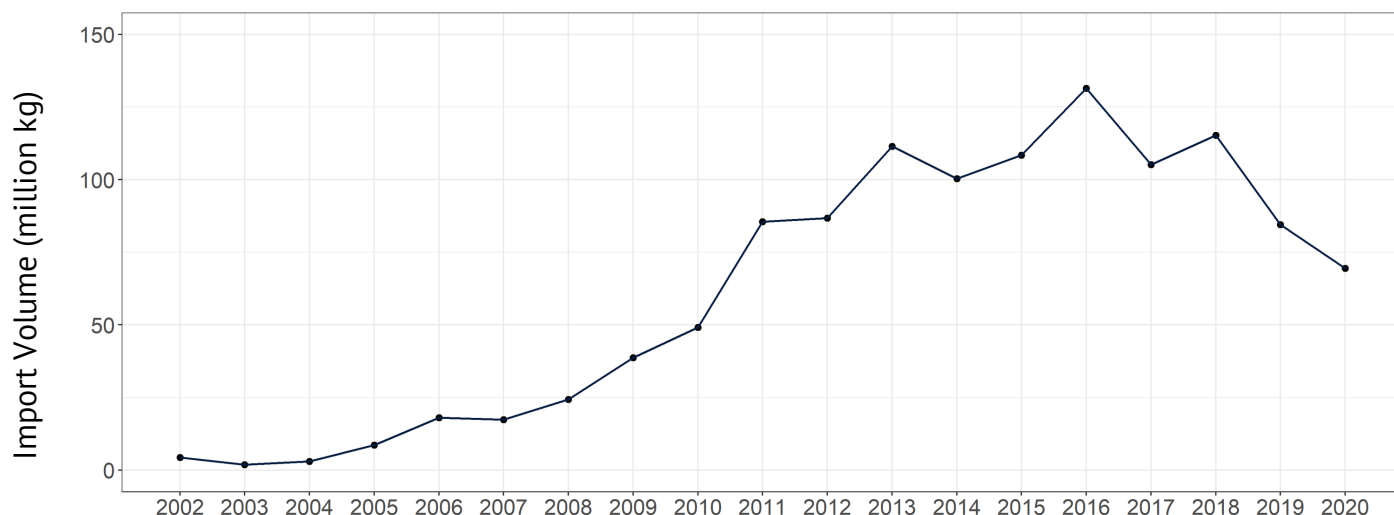
However, the antidumping efforts effectively raised the US domestic price of processed catfish and lowered the Vietnamese export price (Duc, N., 2010), leading to even greater international catfish exports for Vietnam.

Despite several attempts at impeding the imports of catfish from Vietnam, imported catfish-like fillet products have increased their share of the US catfish market from 20% to 80% from 2005 to 2013 (Hanson, 2015).



# BACKGROUND

FIGURE 1: Yearly Catfish Import from Vietnam, 2002 - 2020



## Regulatory Shift from FDA to USDA

Catfish, as well as all seafood, is traditionally regulated by the FDA. However, the Food, Conservation and Energy Act of 2008 required the catfish to be inspected with a higher standard due to health concerns from polluted water in Mekong River by shifting authority to the USDA. The Obama administration held back in implementing the regulatory transition because of considerations in building its alliance with Vietnam under the long-term goal of establishing the Trans-Pacific Partnership to counter the increasing regional influence of China in the Asia-Pacific region (Todd IV, W., 2014).

U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) began regulating catfish on December 2, 2015. FSIS released a final rule establishing an inspection program for fish under the order Siluriformes, including catfish. This inspection program was under a transition period that lasted 18 months for both domestic and foreign producers. Catfish exporters were required until September 1, 2017, to submit documentation, and comply with Hazard Analysis and Critical Control Point (HACCP) requirements and good manufacturing practices according to FDA regulation. Foreign producers which wanted to export catfish to the US, after September 1, 2017, were required to submit equivalence documentation. FSIS had permitted Vietnam, China, and Thailand to continue exporting catfish to the US while they went through the equivalence process.

By the end of 2019, China, Vietnam, and Thailand all acquired equivalence to export raw Siluriformes fish to the US. These granted equivalences opened the American market to 30 foreign catfish producers in the three countries mentioned above.

# DATA & ANALYSIS

## DATA SOURCES

For data of refused catfish products, we used data from the FDA and USDA. FDA data listed all refused products under their authority from 2002 to 2020. The last catfish product refused by the FDA occurred in December 2016. The USDA data listed refused animal products from 2015-2020, showing its first refusal of catfish product in May 2016.

For data on catfish trade volume, we used data from the National Marine Fisheries Service (NSFS) under the National Oceanic and Atmospheric Administration (NOAA). We used data listing monthly trade volume from various countries from 2012 to 2020.

## MODELS

We used linear regression analysis to identify the strength of the effect that shifting regulation from FDA to USDA has on the import refusal rate of catfish.

Model 1:

- Total monthly refusals explained by USDA authority

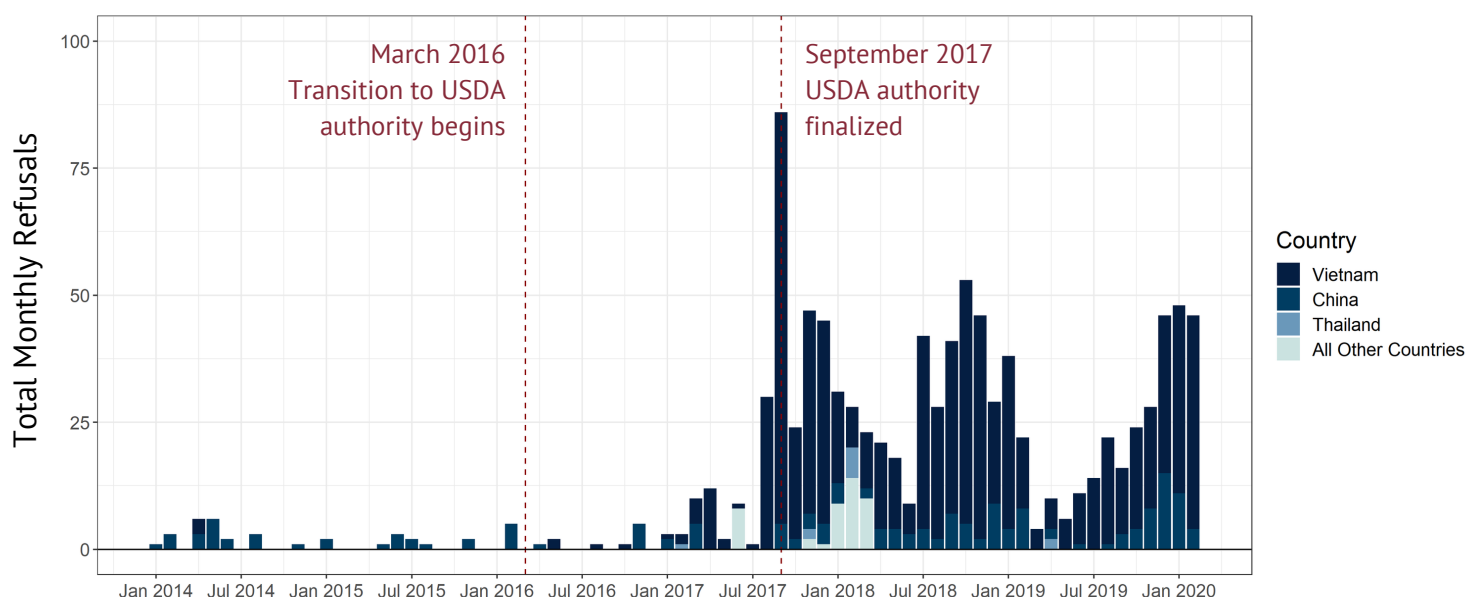
Model 2:

- Total monthly refusals explained by USDA authority, controlling for the transition period, import volume, country of origin, and seasonality.

Model 3:

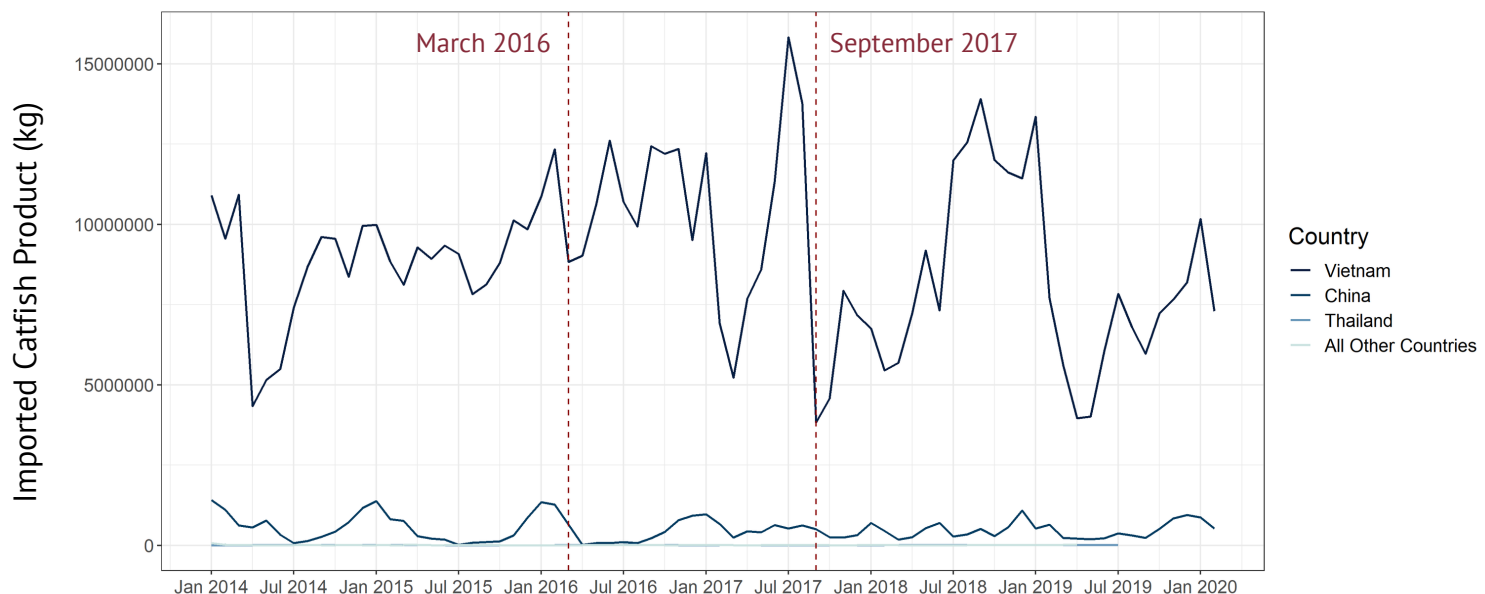
- Monthly food safety refusals explained by USDA authority, controlling for the transition period, import volume, country of origin, and seasonality.

FIGURE 2: Monthly Catfish Refusals from Major Exporters, 2014 - 2020



# DATA & ANALYSIS CONT.

FIGURE 3: Monthly Import Volume from Major Exporters, 2014 - 2020



## FACTORS

Model 1 used only USDA authority to explain refusal rate, essentially comparing the average refusal rate between USDA and FDA authority.

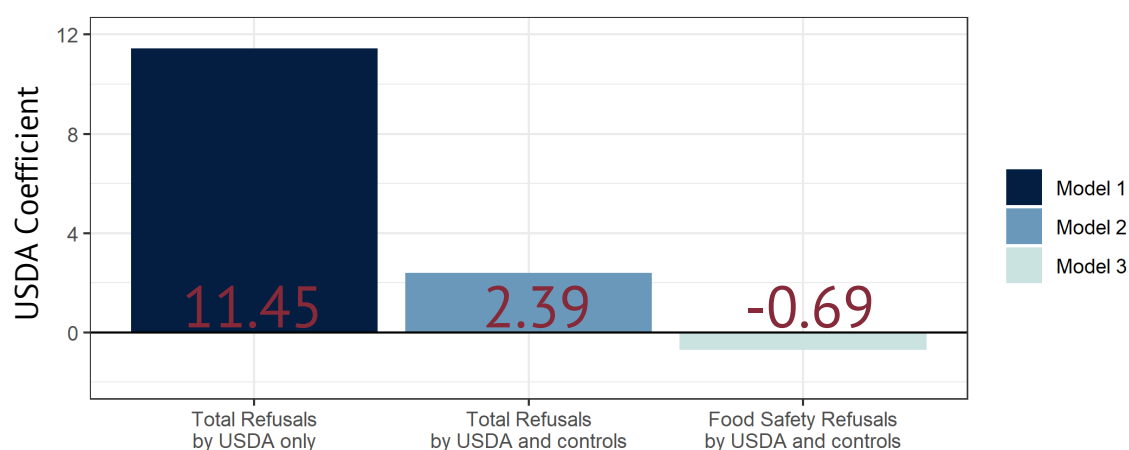
- USDA - This variable represents the data under USDA authority. Months from September 2017 onward are classified as USDA.

Models 2 and 3 control for the following additional factors to isolate the true effect of USDA authority.

- Transition Period - This variable represents data during the transition period from FDA to USDA. Months from March 2016 to August 2017 are classified as transition.
- Import Volume - This variable controls for market demand of catfish products. The better understand the effects of USDA authority, the variable is isolated into import volume under USDA, transitioned authority, and FDA authority.
- Fixed effects controlling for country variation and seasonal variation are added. The model controlled for country variation by adding classifications for Vietnam, China, and Thailand, leaving out a composite group of all other catfish exporting countries, and then for seasonality by adding 11 of the 12 calendar months.

Model 3 limited monthly refusals to only those related to food safety. From the FDA data, products with the following charge codes have been classified as food safety related: 83, 238, 249, 280, 308, 2000, 2860, 3821. While in the USDA data, products with refusal reasons including "Failed Laboratory Analyses" have been classified as food safety related.

## FIGURE 4: The Effect of USDA Authority



## RESULTS

The effect of USDA authority in model 1 demonstrates that on average a single month under USDA authority will have approximately eleven more refusals than under FDA authority. This model does not control for other factors that may influence the refusal rate beyond USDA authority.

Model 2 added controlling factors, providing a better estimate of the effect of USDA authority. Months under USDA authority will have approximately two more refusals compared to FDA authority when considering similar import volume, time of the year, and country of origin.

Model 3 considers food safety-related refusals only and found that USDA authority had a negative effect, approximately one less refusal under USDA authority with comparable circumstances to a month under the FDA.

In each model, the effect of USDA authority was significant and cannot be discounted. Likewise, import volume under USDA authority matters, though only when exporting millions of kilograms of catfish, a degree only seen by China and Vietnam. Model 2 showed that an additional import of one million kilograms of catfish product under USDA authority could yield two more refusals in a month. Meanwhile, model 3 showed that more than an additional ten million kilograms of catfish product under USDA authority could yield one more food safety-related refusal in a month.

By comparison, the effect of the transition period and import volume under non-USDA authority had minimal effects and do not offer additional insights.

For complete statistical results, see page 8.

# CONCLUSION

## CONCLUSION

In shifting import authority from FDA to USDA, catfish products were rejected more often and particularly affected high export countries such as China and Vietnam, as shown by each analysis model. However, it is questionable how substantive of an effect the authority shift truly was. Combining the effects of USDA authority and import volume, an additional one million kg of imported catfish would be required to increase refusals by five in a given month. Comparing the peak of refusals, 86 in September 2017, to the near four million kilograms imported in the same month, and then also considering that USDA refusals often weighed approximately 6 kg, model 2 highlights that while refusals have increased, import demand has not been impeded.

Arguably, the shift to USDA authority led to higher food safety standards in exporting countries, leading to improved trade channels. The negative effect of USDA observed in model 3 implies that refusals due to food safety decreased, in which a plausible explanation could be higher internal sanitation requirements in the process of meeting requirements for FSIS equivalence. As the major exporters ultimately gained equivalence in November, 2019, and continued exporting throughout the process, the decreasing trend of refusals after the shift may correlate to rising regulation standards within the countries themselves. However, the effect of import volume under USDA authority was positive in model 3, which could offset the negative effect of USDA authority itself regarding food safety refusals. This is unlikely as import volume would have to be approximately ten million kilograms to only counteract the negative effect of USDA and the highest amount exported by a single country during USDA authority was fourteen million by Vietnam in September 2018.

This latest maneuver to raise obstacles for catfish exporting countries has found superficial success, definitively reducing imports under USDA authority. However, the paltry amount refused, when compared to trade volume demanded, emphasizes that the enormous bureaucratic effort in shifting regulation authority cannot impede market forces and that this novel policy has not achieved its intended outcome. Additionally, the rapid pace with which countries gained FSIS equivalence further highlights how ineffective these mechanisms were in hindering trade.



# STATISTICAL RESULTS

Table 1:

	(1)	(2)	(3)
USDA Authority	11.45*** (1.74) [ $t = 6.57$ ]	2.39** (0.84) [ $t = 2.83$ ]	-0.69** (0.17) [ $t = -3.98$ ]
Transition Period		0.40 (0.47) [ $t = 0.86$ ]	-0.14 (0.18) [ $t = -0.74$ ]
Import Volume under FDA (million kg)		-0.62 (0.85) [ $t = -0.74$ ]	-0.08* (0.04) [ $t = -2.02$ ]
Import Volume in Transition (million kg)		0.40 (0.23) [ $t = 1.74$ ]	0.08** (0.03) [ $t = 3.09$ ]
Import Volume under USDA (million kg)		2.63*** (0.28) [ $t = 11.06$ ]	0.10*** (0.03) [ $t = 4.80$ ]
Vietnam		5.65 (8.01) [ $t = 0.70$ ]	0.60 (0.38) [ $t = 1.58$ ]
China		0.88 (0.58) [ $t = 1.52$ ]	0.72*** (0.19) [ $t = 3.76$ ]
Thailand		0.06 (0.52) [ $t = 0.11$ ]	-0.05 (0.13) [ $t = -0.35$ ]
Monthly Fixed Effects		In Model, Not Reported	In Model, Not Reported
Constant	0.63** (0.19) [ $t = 3.31$ ]	0.80 (0.61) [ $t = 1.32$ ]	0.15 (0.09) [ $t = 1.76$ ]
$N$	262	262	262
$\hat{\sigma}$	8.32	6.02	0.87
$AdjustedR^2$	0.278	0.622	0.119

Standard errors in parentheses

\* indicates significance at  $p < 0.05$

\*\* indicates significance at  $p < 0.01$

\*\*\* indicates significance at  $p < 0.001$

# GLOSSARY

**ACC**-Affirmation of Compliance Codes. All FDA-regulated products are expected to be in compliance at the time of entry. To help expedite the FDA's review of product compliance, the entry filer can submit additional information at the time of entry, such as registration, listing, and approval numbers.

**BTA**- Bilateral Trade Agreement

**CBP**-U.S. Customs and Border Protection

**CFA**- Catfish Farmers' Association

**DOC** - Import Administration of Department of Commerce

**FDA**-U.S. Food and Drug Administration

**FMIA** -Federal Meat Inspection Act

**FSIS**- U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS)

**FSMA**- Food Safety Modernization Act

**HACCP**- Hazard Analysis Critical Control Point is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

**ITC**-International Trade Commission

**NFI**-National Fisheries Institute

**DOC**- United States Department of Commerce

**USDA**-United States Department of Agriculture

**VASEP**-Vietnamese Association of Seafood Exporter and Processors

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NOAA: <https://www.fisheries.noaa.gov/>