Negative Brief: FSMA Funding

By “Coach Vance” Trefethen

***Resolved: The United States federal government should substantially reform its agriculture and/or food safety policy in the United States.***

The plan increases funding for the Food & Drug Administrations’ Food Safety Modernization Act (FSMA). The AFF argues that the Status Quo budget is underfunding FSMA well below what it needs to function properly. AFF’s expectation is that fully funding this existing law (passed by Congress in 2011) will improve food safety and reduce food-borne illness in the United States.

This brief also contains a Counter Plan. If you decide to run this, run it in the 1NC along with Topicality and Inherency, then run Solvency and Disadvantages against the AFF in 2NC, then refute 2AC attacks on the counterplan in 1NR. But if you don’t want to use it, you can also simply run the arguments above and attack the case with conventional stock-issue refutation.

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CASE NOTES

The plan increases funding for the Food & Drug Administrations’ Food Safety Modernization Act (FSMA). The AFF argues that the Status Quo budget is underfunding FSMA well below what it needs to function properly. AFF’s expectation is that fully funding this existing law (passed by Congress in 2011) will improve food safety and reduce food-borne illness in the United States.

NEGATIVE PHILOSOPHY / COUNTER CRITERION

Regulations must do more good than harm, must solve at least part of the problem, at a justifiable cost

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

For any regulation to produce more good than harm, two factors must be present. First, there must be an actual problem to solve. Second, the regulation has to solve at least part of the problem (and at a cost that is justified by the benefit).

TOPICALITY

1. No “policy” reform

Link: Definition of policy

Merriam Webster Online Dictionary, copyright 2016 <http://www.merriam-webster.com/dictionary/policy>

“a high-level overall plan embracing the general goals and acceptable procedures especially of a governmental body”

Violation: Affirmative isn’t changing the high-level overall plan

Under the Affirmative’s proposal, the high-level overall plan stays the same, we just spend more money on it. They make exactly zero changes to the FSMA legislation itself.

Impact: No Affirmative team

No one in the room today is affirming the resolution. No matter who wins the round, you should write Negative on the ballot.

SOURCE INDICTMENT

FDA artificially inflates numbers to make food risk look greater

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

In implementing the produce safety rule, the FDA has insisted on covering all fruits and vegetables that are commonly consumed raw (see table 3). However, a few commodities account for most of the fruit and vegetable outbreaks in almost every year: herbs (e.g., basil, parsley), whole and especially fresh-cut leafy greens (e.g., lettuce, spinach), melons (e.g., cantaloupe, honeydew), alfalfa sprouts, and tomatoes (whole and fresh-cut). According to the FDA, over a six-year period those commodities accounted for 17 of 22 of outbreaks and 59 percent of illnesses associated with fresh fruits and vegetables. The remaining five outbreaks and illnesses are associated with other products. From 2003 to 2008 (the years that the FDA uses for its data), the other products associated with outbreaks were raspberries/blackberries, raw almonds, green onions, jalapeño/serrano peppers, and snow peas. In what appears to be a blatant attempt to inflate its benefits estimate with no supporting evidence, the FDA uses those few other products as proxies for all other fruits and vegetables. The FDA takes the point of view in the produce rule that because outbreaks are possible—even though they are not probable—they should be covered. That regulatory philosophy pervades the FSMA rules: the regulations overreach by attempting to control all possible problems, no matter how improbable they may be.

INHERENCY

1. FSMA got new finding as of December 2015.

They got 95.4% of the funding they asked for ($104.5 million out of $109.5 m), and it will be enough

Michael Taylor 2016 (FDA *Deputy Commissioner for Foods and Veterinary Medicine) 11 Jan 2016 “*FSMA Implementation: The Road Is Challenging, but the Company Is Extraordinary” <http://blogs.fda.gov/fdavoice/index.php/2016/01/fsma-implementation-the-road-is-challenging-but-the-company-is-extraordinary/>

We’re in a good place with the FSMA rules. Five of the seven rules we proposed have now been finalized, and we intend to publish final regulations on sanitary transportation and intentional adulteration in the spring. President Obama’s Fiscal Year 2016 budget request for FSMA implementation was close to fully funded, with FDA set to receive $104.5 million of the $109.5 million requested. This critical funding will enable us to maintain our momentum toward timely, comprehensive implementation.

Congress did the AFF plan in December 2015: they boosted funding for FSMA

Sandra Eskin 2015 (*directs The Pew Charitable Trusts' work on food safety*) “Congress Approves Historic Increase in Food Safety Funding” 18 Dec 2015 <http://www.pewtrusts.org/en/research-and-analysis/analysis/2015/12/17/congress-approves-historic-increase-in-food-safety-funding>

In a victory for American consumers, the omnibus spending bill passed by Congress on Dec. 18 included an additional $104.5 million for the U.S. Food and Drug Administration to continue implementation of the FDA Food Safety Modernization Act (FSMA). The funding boost is the largest for the agency’s FSMA-related work since the groundbreaking law was enacted nearly five years ago. The added resources for fiscal year 2016 will support efforts to educate food growers, processors, and importers about their new responsibilities under the law. Funds will also enable FDA to ramp up its enforcement capacity so that it is ready when the recently finalized FSMA rules come into effect.

1. More money for FSMA not needed – budget and personnel already large

FDA budget and personnel have skyrocketed since FSMA, it’s just an excuse to whine about more money

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

Understandably, members of Congress, like consumers, are concerned about food safety issues, but the evidence did not support passage of the FSMA requiring federally mandated preventive controls. The FSMA appears merely to offer an opportunity for the FDA to expand its size and influence. Predictably, the FDA has used the FSMA to make a strong case for more funding. As noted in a report coproduced by the Regulatory Studies Center at George Washington University, “The Food and Drug Administration, which added an estimated 1,731 new personnel in 2014, is set to add another 1,033 people in 2015” and “Its budget has risen by $1.8 billion—or 45 percent—since passage of the Food Safety Modernization Act in 2011.”

HARMS / SIGNIFICANCE

1. No food risk big enough to justify FSMA regulations

FDA has never demonstrated a problem significant enough to justify FSMA

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

To justify the establishment of a federal regulation, an agency cannot simply identify a problem. Instead, there should be evidence of a large, recurring problem that is not likely to go away without a federal solution. In fact, Executive Order 12866 (President Bill Clinton’s order still in effect) demands that “each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new regulatory action) as well as assess the significance of that problem.” The executive order is the president’s instruction to regulatory decision makers about how he expects them to make policy decisions. But in rulemaking for the FSMA, the FDA has been unable to identify a significant problem to justify some of the regulations as required by the ruling executive order.

SOLVENCY

1. No cost-benefit analysis

Link: Affirmative reads no evidence that the costs of FSMA would exceed the benefits

Impact: We shouldn’t adopt regulations until cost-benefit studies prove the true value of the policy

James Gattuso & Diane Katz 2016 (both are *Senior Research Fellows in Regulatory Policy*  
*Thomas A. Roe Institute for Economic Policy Studies*) Red Tape Rising 2016: Obama Regs Top $100 Billion Annually <http://www.heritage.org/research/reports/2016/05/red-tape-rising-2016-obama-regs-top-100-billion-annually>

However, agencies very often fail to quantify the costs—and overstate the benefits—of their rules. In some cases, this is unavoidable because costs cannot always be quantified (for instance, for technologies not invented or the loss of religious freedom). But in many instances in 2015, as in years past, agencies simply failed to conduct a cost analysis. Exacerbating matters, independent agencies are exempt from the Executive Order. For example, there was no analysis prepared by the Federal Reserve System for its regulatory capital rules although it requires the largest bank holding companies to retain an additional $200 billion as a buffer against losses. Likewise, as discussed above, the FCC did not analyze the cost of its Internet regulation despite the potential for massive effects on network investment. The absence of cost analyses represents a major dysfunction in the rulemaking process. How is the public to judge the efficiency of a regulation or hold agencies accountable for effectively managing a problem if the costs of a rule are estimated to range, say, from $290 million to $2.05 billion—as was the case with a rule setting margin requirements for uncleared swaps promulgated by the Commodity Futures Trading Commission?

A/T “Human life has infinite value, so we can spend anything to save 1 life” – No, life does not have infinite dollar value

If all risks to human life must be eliminated no matter the dollar cost, we need to immediately ban automobiles, since they kill thousands of people every year. That would save far more lives than the Affirmative plan and would uphold this value they claim they support. The reason we don’t is because as a society, we have judged that the economic value of cars outweighs the lives lost each year. That trade-off proves that rational people don’t really believe human life has infinite economic value.

1. No evidence of FSMA success

FDA has no evidence that FSMA will provide any substantial degree of food risk reduction

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

Despite the high cost of complying with all those regulations, the FDA has been unable to show that significant systematic public health risks warrant some of these regulations or, in other cases, indicate that where such risks exist, the rules will make much of a difference. In fact, experience with mandating preventive controls in previous similar FDA regulations indicates that the FDA has overestimated the benefits of these new regulations. As might have been predicted, the FDA has no evidence that the new regulations will reduce foodborne risk to any degree that would make them worthwhile.

1. Missing steps

FDA is missing key steps in the food safety process. Result will be ineffective at reducing fresh produce risks

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

In 1995, the FDA estimated that the number of cases of Vibrio vulnificus–related illnesses would be reduced from 60 cases to between 30 and 48 per year. In 2011, the Centers for Disease Control and Prevention reported 113 cases of illness caused by Vibrio vulnificus. Just as the FDA’s seafood HACCP rule failed to reduce the risk associated with seafood that was not subject to a kill-step, one can expect that establishing preventive controls for fresh produce that include no heat treatment between the farm and the family table will likewise be ineffective at reducing fresh produce risks.

1. More study needed

Before implementing FSMA regulations, more study should be done, since current evidence is not sufficient to justify FSMA

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

Congress should use the information provided by comments, including this paper, and the information that the FDA will produce for the mandated risk assessments to revisit the provisions in FSMA. Congress should move quickly to eliminate the statutory deadlines, put a hold on any FDA rules going final, and carefully re-examine the provisions to see which rules may potentially be functional. A functional rule is one that addresses a real systemic problem and has benefits that exceed the costs.31 Such action seems particularly necessary given that the FDA has already been sued over its failure to adhere to congressionally mandated timelines as well as 31 If the rules are to be as efficient as possible, the regulatory option should be selected for which benefits exceed costs by the maximum amount. In order to choose the right overall regulation, each requirement within the regulation needs to be evaluated separately for benefits and costs. 19 the fact that there is a dearth of evidence that shows either problems or solutions in the areas I have addressed above.

DISADVANTAGES

1. Negative Net benefits. The costs of FSMA exceed the benefits

FSMA either doesn’t address the real risks or doesn’t actually solve the risks it addresses. So, its costs exceed its benefit

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

There are two problems with these regulations and the expansions proposed in the FSMA: either they do not address an actual food safety risk in the areas they cover, or, where there is a significant risk, analysis shows that they will not effectively reduce that risk. Either way, the costs of these rules exceed the benefits, in some cases by a great deal.

Since the US food supply is already very safe, the small potential benefits aren’t worth the cost

James Gattuso & Diane Katz 2016 (both are *Senior Research Fellows in Regulatory Policy*  
*Thomas A. Roe Institute for Economic Policy Studies*) Red Tape Rising 2016: Obama Regs Top $100 Billion Annually <http://www.heritage.org/research/reports/2016/05/red-tape-rising-2016-obama-regs-top-100-billion-annually>

Congress dramatically expanded government control over the nation’s food supply in 2011 with passage of the Food Safety Modernization Act, and it has taken some five years to develop the regulations that dictate how the federal government expects farmers to produce fruits and vegetables (and dog food), including rules governing soil, water, hygiene, packing, temperatures, and even what animals may roam which fields and when. It also increased inspections of food “facilities” and taxes them to do so. Foodborne illness is indeed a public health concern. However, America’s food supply is remarkably safe, and yet the Food and Drug Administration (FDA) has cast an exceedingly broad regulatory net rather than focusing on the biggest risks. That means higher food costs across the board without regard to consumer benefit. In addition to consumers, the biggest burden will fall on small farms and “local” food producers who are forced to implement controls, training, and record-keeping systems fashioned for much larger operations.

1. Huge economic costs

FSMA will cost $2 billion to $3 billion or more to the US economy in regulatory burden

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

The FDA’s own preliminary estimates predict that the regulations required by the FSMA as written by the FDA would cost well over $2 billion on an annualized basis (see table 1). According to the FDA estimates, costs in the first year of implementation will be well over $3 billion. Those estimates may be low for a number of reasons. For example, the FDA foreshadowed that it might add a number of additional regulatory provisions to the final rules (the costs of which were not included in the estimates of the proposed rules). Further, the FDA’s estimates might not include many of the costs of following the regulations that the food industry has identified in its comments on the regulations.

1. Increased food safety risk

FSMA regulations are so burdensome that they distract efforts from critical points and could actually reduce food safety

Richard A. Williams 2015 (Senior Research Fellow and Vice President of Policy Research for Mercatus Center at George Mason University) Aug 2015 “Regulations Implementing the Food Safety Modernization Act” <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>

In the FSMA preventive controls paradigm, preventive controls are established throughout the production process, not just at critical control points. The FSMA paradigm significantly multiplies the number of points in the process at which businesses will be expected to expend more resources. Businesses that have already successfully implemented a HACCP system would still need to establish preventive controls at more points in the production process to satisfy FSMA, despite the lack of evidence that extra monitoring would provide additional benefits. If attention became divided between critical and noncritical points in the production process, the outcome could be less safe than in the existing system.

OPTIONAL COUNTERPLAN

[Note: If you decide to run this, run it in the 1NC along with Topicality and Inherency, then run Solvency and Disadvantages against the AFF in 2NC, then refute 2AC attacks on the counterplan in 1NR. But if you don’t want to use it, you can also simply run the arguments above and attack the case with conventional stock-issue refutation.]

We deny the resolution and the Affirmative plan, and instead propose the following Counterplan to take effect the same date as proposed in the Affirmative plan:

1. The 50 states reject FSMA and refuse to cooperate with it.
2. The added FSMA funding already granted by Congress and any funding proposed by the Affirmative are revoked and used to reduce the federal deficit.

Our Counterplan promotes good debating because it denies the resolution and is exclusive to the Affirmative plan. We do a minor repair to the funding of an existing federal policy, without reforming the policy itself, and we change State agriculture policies. Both of these are non-topical, so our Counterplan does not affirm the resolution. And we have good clash because it’s impossible to do both our plan and the Affirmative at the same time. Their plan depends on States cooperating with FSMA, which we block, and you can’t reduce funding for FSMA and increase it at the same time.

1. The Counterplan is offered conditionally. We will give you 2 independent reasons to vote against the Affirmative plan. If FSMA is good, and since the Status Quo has already done their plan, you can vote Negative on that alone and FSMA will solve their harms. But if you’re convinced that FSMA is bad, after we read our disadvantages to FSMA, then you can vote for the Counterplan and block FSMA’s implementation. Here are the Justifications for the Counterplan:

COUNTERPLAN JUSTIFICATION 1. States’ rights violated

Link: Federal food safety regulations are exceeding federal authority and violating federalism and the rights of the states

Pete Kennedy 2016 (attorney) “FDA Taking Over State Food Regulation” 26 Apr 2016 <http://www.farmtoconsumer.org/blog/2016/04/26/fda-taking-over-state-food-regulation/>

What [**happened**](http://www.farmtoconsumer.org/blog/2016/02/10/who-makes-law-in-virginia-fda/) in the 2016 Virginia legislative session is an example of how FDA is controlling state food regulation through the food code. A bill that would have legalized the unregulated sale of potentially hazardous baked goods (foods subject to time and temperature control, e.g. pumpkin pies) was killed after the Virginia Department of Agriculture and Consumer Services (VDACS) informed members of a legislative subcommittee that the bill was in violation of the FDA Food Code. The bill was initially passed by the same subcommittee one week earlier. Virginia has adopted the food code which calls for regulation of potentially hazardous food such as baked goods. In 2015, VDACS received $70,000 from FDA under the “Advancing Conformance” funding opportunity. These cooperative agreements violate principles of federalism and separation of powers, amounting to unelected bureaucrats making law.

Impact: Better results. Policy experimentation among diverse states develops new and better ideas

Prof. Graeme Boushey 2012. (Robert Wood Johnson Scholar in Health Policy Research at the University of Michigan and assistant professor at Univ of California, Irvine. ) Punctuated Equilibrium Theory and the Diffusion of Innovations POLICY STUDIES JOURNAL, January 2012 <http://onlinelibrary.wiley.com/doi/10.1111/j.1541-0072.2011.00437.x/full>

Although federalism makes policy coordination difficult, it also creates opportunities for considerable policy innovation, as municipal, county, and state governments develop new policies to address local concerns. Federalism encourages venue shopping, a process where activists and interest groups strategically exploit the multiple venues of government to secure support for their legislative programs ([Baumgartner & Jones, 2009](http://onlinelibrary.wiley.com/doi/10.1111/j.1541-0072.2011.00437.x/full#b3); [Holyoke, 2003](http://onlinelibrary.wiley.com/doi/10.1111/j.1541-0072.2011.00437.x/full#b21); [Pralle, 2003](http://onlinelibrary.wiley.com/doi/10.1111/j.1541-0072.2011.00437.x/full#b37)). This process increases the number of new ideas entering the political systems and can create conditions where “new ideas or policy images may spread rapidly across linked venues, thus setting in motion a positive feedback process” ([Baumgartner & Jones, 2009](http://onlinelibrary.wiley.com/doi/10.1111/j.1541-0072.2011.00437.x/full#b3), p. 240).

COUNTERPLAN JUSTIFICATION 2. Counterplan advocacy.

State refusal would block FSMA and create advantages by avoiding FSMA problems

Pete Kennedy 2016 (attorney) “FDA Taking Over State Food Regulation” 26 Apr 2016 <http://www.farmtoconsumer.org/blog/2016/04/26/fda-taking-over-state-food-regulation/>

FDA needs the help of state agencies to implement and enforce the FSMA requirements; the agency does not have close to the manpower needed to enforce FSMA on its own. FDA will be entering into more cooperative agreements than ever to get state help on FSMA;11 states will be spending more of their time enforcing federal law and less enforcing their own laws. State agencies will be increasingly conscripted by the federal government. There are numerous ways to fight back against FDA’s attempts to control all food regulation through FSMA and other means; these include cutting FDA’s funding for FSMA implementation, state laws establishing stricter oversight and standards for cooperative agreements between FDA and state agencies, state food freedom bills legalizing unregulated producer to consumer direct commerce, and piece meal amendments to FSMA. If this doesn’t happen, the industrial food system will further consolidate its control over the food supply; imports will sharply increase; food security, self-sufficiency and food production will be a pipedream; and the local food system won’t come close to meeting the demand for its products.

COUNTERPLAN JUSTIFICATION 3. Deficit reduction

Every increase in the deficit hurts the economy

Dr William Gale and Benjamin Harris 2011. (Gale - PhD in economics, Stanford Univ.; senior fellow at the Brookings Institution and co-director of the Urban-Brookings Tax Policy Center; former assistant professor in the Department of Economics at UCLA, and a senior economist for the Council of Economic Advisers under President George H.W. Bush; Harris - master’s degree in economics from Cornell University and a master’s degree in quantitative methods from Columbia University; senior research associate with the Economics Studies Program at the Brookings Institution) “A VAT for the United States: Part of the Solution” <http://www.taxanalysts.com/www/freefiles.nsf/Files/GALE-HARRIS-5.pdf/$file/GALE-HARRIS-5.pdf>

But even in the absence of a crisis, sustained deficits have deleterious effects, as they translate into lower national savings, higher interest rates, and increased indebtedness to foreign investors, all of which serve to reduce future national income. Gale and Orszag (2004a) estimate that a 1 percent of GDP increase in the deficit will raise interest rates by 25 to 35 basis points and reduce national saving by 0.5 to 0.8 percentage points of GDP.

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