



## Regulation Review

# Final Food Distribution Safety Rules

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The Food and Drug Administration (FDA) recently published a set of rules that would finalize new standards for how food distributors package and transport products. The regulations stem from the Food Safety Modernization Act (FSMA). The rules have had a winding road through the rulemaking process

as some of them have required an additional round of proposed rulemaking. The American Action Forum (AAF) previously reviewed the most current proposed version [here](#). Combined, the three final rules' unofficial, pre-publication versions are 1,661 pages.

## BREAKDOWN

### [“Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” \(FSVP\)](#)

- [Final Rule Annualized Costs](#): \$435 Million (+\$38 Million from proposed version)
- Final Rule Total Costs: \$3.06 Billion (Over 10 years, Discounted at 7%)
- Final Rule Paperwork: 616,506 Hours

### [“Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”](#)

- [Final Rule Annualized Costs](#): \$366 Million (-\$20 Million from proposed version)
- Final Rule Total Costs: \$2.57 Billion (Over 10 years, Discounted at 7%)
- Final Rule Paperwork: 1,492,346 Hours

### [“Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications”](#)

- Final Rule Annualized Costs: \$11.6 Million
- Final Rule Paperwork: 14,172 Hours

## ANALYSIS

The “Accreditation” rule is a relatively minor part of this overall regulatory package, but the other two rules are quite significant. Combined, the two rules will add roughly \$5.6 billion in total final rule costs to 2015's overall tally. Individually, the rules represent the 8th and the 9th most expensive regulations of the year so far. It could have been more dramatic on the cost side though; the original proposed versions both had higher annual costs.

Given these annual costs, it is hardly surprising that both rules contain unfunded mandates on the private sector that exceed the Unfunded Mandates Reform Act threshold and “will have a significant economic impact on a

substantial number of small entities” (SISNOSE) under the Regulatory Flexibility Act (RFA). In particular, the RFA analysis examines the impact these rules would have on small entities. Although both rules do include certain exemptions for small entities, they will still affect many small businesses.

According to the final “Regulatory Impact Analysis,” roughly two-thirds of affected entities under the FSVP rule are “Very Small Importers.” That analysis does not include a direct examination of per-entity costs burdens for “Very Small Importers,” but claims that it should “remain similar to the burden described in the IRFA [Initial Regulatory Flexibility Analysis].” That [analysis](#) found that the “burden of the proposed rule would exceed one percent of average annual sales, a significant economic effect in this industry, for importers in the retail trade industry and certain very small importers.” Even more striking is the admission that this regulation could make “it is possible that some small importers would be forced to shut down or look for other importing markets.”

For the “Standards for Growing...” rule, FDA finds that that per producer costs for “very small” and “small” producer costs amount to 4 percent and 3 percent of total sales, respectively. This may seem relatively minor, but for perspective, [other agencies](#) regularly set their cost-to-revenue threshold for “significant economic impact” at 3 percent. In addition, it is important to note that the vast majority of small farms operate with a [profit margin of under 10 percent](#). This rule could essentially consume at least one third of their profits.

These rules will necessarily affect agriculturally-centric states. Below is an illustration of the state breakdowns for each rule. For the FSVP rule, using Census data on “Food Manufacturing” (as FDA did), the following states will see the most dramatic impacts:

State	Cost Burden (\$ Millions)
California	\$398
New York	\$238
Texas	\$199
Pennsylvania	\$139
Illinois	\$138

For the “Standards for Growing...” rule, the breakdown comes from using [Department of Agriculture data](#) on the number of farms affected. The state-level cost burden for that rule is the following:

State	Cost Burden (\$ Millions)
Texas	\$303

State	Cost Burden (\$ Millions)
Missouri	\$121
Iowa	\$109
Oklahoma	\$98
California	\$94

These regulations could also have an impact on the consumer level. According to the “Standards for Growing...” rule, “if 100 percent of the costs of this rule were passed along directly to consumers this would increase the market price for fresh produce by only 2.1 percent.” Last year, the average household spent [roughly \\$4,000](#) on “food at home.” This rule could essentially amount to an additional \$83 in extra expenditures for the typical household next year. This may not seem like much on an annual scale, but it amounts to more than one and a half [typical Thanksgiving dinners](#).

Maintaining a safe food supply throughout the distribution chain is important. However, it is worth noting the costs of new rules that affect food production and transportation. These rules will be some of 2015’s most expensive on both the macro level for the country and the micro level for small businesses and consumers.