



## Regulation Review

# Food Safety Redux II

SEPTEMBER 22, 2014

FDA's second set of food safety rules covers "Verification Programs for Importers of Food for Humans and Animals," and "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." AAF reviewed the first set of proposed rules [here](#) and [here](#). The regulatory impact analyses for the rules are [here](#) and [here](#).

## BREAKDOWN

- Foreign Supplier Annualized Cost: \$397 million (\$3.9 billion NPV)
  - \$64 million less than original proposal
- Foreign Supplier Annual Paperwork: 2.9 million hours
  - 386,385 hours less than original proposal
- Human Food Safety Standard Annualized Cost: \$386 million (\$2.7 billion NPV)
  - \$73 million less than original proposal
- Human Food Safety Standard Annual Paperwork: 1.1 million hours
  - 92,590 hours less than original proposal

## ANALYSIS

The Foreign Supplier Verification re-proposal is based on "extensive public input" from the last round of proposals, according to FDA. The revised standards ensure that suppliers analyze hazards that are "known or reasonably foreseeable." The measure also requires that suppliers analyze pathogens in some "ready to eat" food. If a foreign supplier farm does not have to comply with safety regulations in their country of jurisdiction, the U.S. importer must obtain biennially written assurances that the foreign farm is complying with FDA rules.

The Standards for Growing and Holding Food proposal provides less testing of untreated ground and surface water and it would allow a farmer to meet water testing requirements using their own test results or those of a third party. The measure also gives FDA several options before it withdraws qualified exemptions for farmers, including warning letters, recalls, and injunctions. Farmers facing withdrawals must have an opportunity to respond to FDA.

Not surprisingly, both rules are considered "economically significant" and both trigger the Unfunded Mandates Reform Act.

## SMALL BUSINESS IMPACTS

In its Foreign Supplier Verification proposal, FDA revised upward the definition of “very small business” to \$1 million, from the \$500,000 threshold in the previous proposal, but still concluded that rule would significantly affect small businesses. The analysis goes on to note that despite the higher threshold, more than 56,000 food importers are still covered under the regulation.

In the Standards for Growing and Holding Food measure, FDA concludes that it “will have a significant economic impact on a substantial number of small entities.” The agency generally assumes that this type of classification will reduce profits or increase prices by three to five percent. According to FDA and the Small Business Administration, 95 percent of farms that grow regulated produce are considered “small.”

However, the proposal also lessens burdens on farms with \$25,000 or less in produce sold and small farms would have an additional two years to comply with most provisions of the regulation.

## STATE IMPACTS

Neither rule provides the specific regulated industry, but given the nature of the rules, there are a few hints at the distributive impact.

For example, the Standards for Growing and Holding Food primarily affects farms. Based on Census data, here is how the following states could be impacted based on possible net present value costs:

<u>State</u>	<u>Possible Cost</u>
California	\$391 million
New York	\$185 million
Texas	\$149 million
Illinois	\$138 million
Pennsylvania	\$131 million
Wisconsin	\$112 million
Ohio	\$106 million
Michigan	\$91 million
New Jersey	\$91 million

<u>State</u>	<u>Possible Cost</u>
Florida	\$79 million

## CONCLUSION

Once regulators publish these revised measures, FDA's burdens for 2014 will eclipse \$15 billion in costs and 7.6 million paperwork burden hours. It's a positive sign that the agency has shown the flexibility to go back to the drawing board and revise these controversial rulemakings. However, time will tell if FDA is more interested in good analysis than rushing to implement a regulation for the sake of another federal placeholder in food safety.