



Regulation Review

Food Safety Redux: Final

SEPTEMBER 14, 2015

The Food and Drug Administration (FDA) recently released a final set of revisions for “Risk-Based Preventive Controls” for [human food](#) and [animal food](#). Together, the two regulations are 1,596 pages and will cost \$4.7 billion. The American Action Forum (AAF) reviewed the revised proposed rules [here](#).

BREAKDOWN

- Human Food Production Costs: \$3,258 million (\$382 million annually)
- Human Food Production Paperwork: 6.2 million hours
- Animal Food Production Costs: \$1,450 million (\$170 million annually v. \$138 million in benefits)
- Animal Food Production Paperwork: 1.1 million

ANALYSIS

Despite the substantial impact and the reality that the costs of the animal food rule exceed the benefits, the administration nevertheless blessed both measures. Curiously, even after implementation and assuming the human food rule works as planned, there will still be hundreds of thousands of foodborne illnesses every year. According to the administration, processed foods covered by the rule cause 903,000 illnesses annually. For the rule to be cost effective, it needs to prevent 157,000 illnesses annually, or 17 percent. This is hardly a ringing endorsement of the regulation.

For the animal food rule, regulators implemented new standards on personnel, facilities, sanitation, plumbing, and amended processes for holding and distribution. Each covered facility must establish specific requirements for: a food safety plan, a hazard analysis, monitoring, corrective actions, supply-chain oversight, a recall plan, and records management.

For the human food rule, the requirements are virtually identical. Food processing facilities will also need to establish a hazard analysis and risk-based preventive controls. In addition to the above requirements, facilities must reanalyze the food safety plan at least once every three years.

On the domestic production side, using [Census data](#) to track the overall distribution of domestic food manufacturers, the following states could bear the largest cost burdens from the two rules:

<u>State</u>	<u>Total Combined Costs (in millions)</u>
California	\$612

<u>State</u>	<u>Total Combined Costs (in millions)</u>
New York	\$366
Texas	\$306
Pennsylvania	\$214
Illinois	\$212
Wisconsin	\$173
Florida	\$168
Ohio	\$166
New Jersey	\$164
Michigan	\$142

Not surprisingly, for rules of this magnitude, both measures trigger the Unfunded Mandates Reform Act (UMRA), as they both impose annual burdens exceeding \$144 million. For perspective, just four other final rules this year have triggered UMRA: “[Waters of the United States](#),” a Medicare payment rule, Underground Storage Tank revisions, and the Renewable Fuels Standard.

Both rules had to take special consideration of the impact on small farms and businesses. Under the Regulatory Flexibility Act, the administration confirmed that small businesses with fewer than 20 employees would bear significant costs from the two rules. In bureaucratic jargon: “[T]he final rule will have a significant economic impact of a substantial number of small entities.” For the Animal Food Production measure alone, per entity costs could reach \$34,000. For perspective, the average animal food manufacturing payroll for a facility in Massachusetts was just \$531,250 in 2013. This could translate into a regulatory tax of roughly six percent for some businesses.

Once finalized, these rules will push 2015 regulatory costs past \$155 billion. After a winding regulatory path that saw a proposed rule, a rescission of that proposal, a new proposed rule, and now a final rule, the resulting costs are nearly identical. Annual costs for the initial proposals topped \$600 million; the final version will impose \$520 million annually. The test now is to determine if these rules will prevent more than 157,000 annual outbreaks, as they claim.