Regulation Review

Food Safety Redux I

SEPTEMBER 22, 2014

The Food and Drug Administration (FDA) recently released a set of revisions to four food safety rulemakings it had previously proposed over the past two years. Two of the rulemakings affect "Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls" for human food and animal food. Together, the two proposals are 350 pages.

FDA states that it has produced these revised versions because, "public comments led to significant changes in our current thinking on certain key provisions of this proposed rule." AAF previously reviewed the original versions here and here. A main part of this rule is the exemption for "very small businesses." The previous iterations both had a series of potential options for what constituted a "very small business," each imposing a different level of costs. In these recent proposals, FDA sets the threshold of sales of less than $1 million dollars for human food producers and $2.5 million for animal food producers.

BREAKDOWN

Original Version:

- Human Food Production Potential Costs: $3.3 billion ($475 million annually)
- Animal Food Production Potential Costs: $1.3 billion ($128 million annually)

Revised Version:

- Human Food Production Costs: $2.6 billion ($371 million annually)
- Animal Food Production Costs: $690 million ($69 million annually)
- Human Food Production Additional Paperwork: 74,692 hours
- Animal Food Production Additional Paperwork: 79,246 hours

ANALYSIS

The shifts from the original versions to the supplemental versions appear to bring steep decreases in costs. This is largely due to FDA settling on a particular threshold for what constitutes a "very small business." The original versions contained a threshold of $250,000 in annual sales. That figure would cover a significantly higher number of entities, thus pushing the aggregate cost higher. However, when one compares apples to apples, this apparent reduction actually masks increasing costs.

In both supplemental proposals, FDA admits that the costs will increase from the original estimates of the $1

million threshold for human food and $2.5 million threshold for animal food. The former will bear an increase of $52 million annually, while the latter will see an additional $4 million annually. For both rulemakings this is because:

> Facilities subject to subpart C institute risk-based environmental monitoring, product testing, and a supplier program as appropriate to the food, the facility and the nature of the preventive controls, and controls to help prevent hazards associated with economically motivated adulteration.

These additional requirements are also responsible for an additional 153,938 hours of paperwork annually across both rules.

It is also worth noting that these revised estimates only focus on domestic entities. There are costs for foreign manufacturers as well. Each of the rulemakings notes that these costs will pass through to domestic consumers in the form of higher prices. Total annualized costs rise by $100 million dollars for the human food rule and $24 million for the animal food rule.

However, on the domestic production side, using Census data to track the overall distribution of domestic food manufacturers, the following states could see the largest cost burdens between the two rules:

State	Total Combined Costs (in millions)
California	$435
New York	$256
Texas	$212
Pennsylvania	$150
Illinois	$148
Wisconsin	$121
Florida	$119
Ohio	$115
New Jersey	$114

State	Total Combined Costs (in millions)
Michigan	$99

Based on public input, FDA decided to settle on less costly options. However, the addition of further requirements means that its estimates increased from the commensurate figures in the original. Furthermore, each of the revised proposals' Regulatory Impact Analyses (found here and here) readily admits that:

> Based on the comments that we received, we anticipate improving our cost estimates to more accurately reflect real world practices. We anticipate that most, although not all, of the adjustments that we will make will increase our estimate of the cost of the regulation.

If FDA can settle on a relatively less costly option in the proposed stage, they might be able to determine a more efficient final version as well.