Regulation Review

Regulation Review: FDA Safety Standards for Animal Food

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Earlier this year, the Food and Drug Administration (FDA) released new regulations on the production of human food under the Federal Food, Drug, and Cosmetic Act. This week, they've released a similar rulemaking that instead focuses on the production of food for animals. The unofficial, pre-publication version of the proposed rulemaking is 405 pages.

Like the human food proposal, this rulemaking will establish guidelines for how producers test for potential hazards in the food. However, as the product in question is for animals and not humans, it does not require producers to look at such factors as the potential for allergens. In addition, although FDA admits that this rule will impose particular burdens on small businesses, it does carve out certain exemptions based upon business size.

BREAKDOWN

- Total Costs: $1.28 Billion (over 10 years)
- No Quantified Benefits Estimate

ANALYSIS

One of the most curious aspects of this proposal is how FDA handles its cost estimate. In the proposed rule itself, the agency only lists the costs as potentially reaching $95 million annually. However, in both the Regulatory Impact Analysis (RIA) and FDA's "fact sheet" on its own webpage, the total costs exceed $128 million per year.

The missing $33 million is the cost to foreign manufacturers. But as the agency explains in the RIA: "Assuming that some part of this foreign cost increase is passed on to US consumers, the annualized cost total to the US market (including domestic and foreign manufacturers) could be as high as $128.75 million." FDA makes no mention of the $128 million estimate in the actual proposal, though the agency knows it will affect U.S. consumers.

At more than $1.2 billion, this proposal is still $2 billion less expensive than its human food counterpart. This is hardly surprising of course, as animal food doesn't need to undergo the same sort of rigorous procedures as human food might. And although the costs are substantial, it is only the 15th most expensive rule published this year. According to FDA's analysis, it imposes an unfunded private sector mandate and is a major rule under the Small Business Regulatory Enforcement Fairness Act.

In its Regulatory Flexibility Analysis, FDA determines that the rule "will have a significant economic impact on a substantial number of small entities." The agency does not quantify "significant economic impact," but other

regulations define it as a rule that raises prices or reduces revenues by three to five percent. For one affected industry, “Rendering and Meat Byproduct Processing,” all entities are considered small businesses, employing fewer than 500 workers. Based upon Census data, the following states have the highest concentrations of industries affected by this proposal:

State	Establishments
California	5,226
New York	2,516
Texas	2,307
Florida	2,136
Illinois	2,048

The above table aligns closely with population trends. This is likely due to the inclusion of broad classifications like “Farm Product Raw Material Merchant Wholesalers” and “Miscellaneous Nondurable Goods Merchant Wholesalers” in the industry sample. Adjusting for those and including only production yields the following distribution:

State	Establishments
California	147
Texas	133
Iowa	110
Pennsylvania	105
Wisconsin	90