

FDA'S ANIMAL FOOD REGULATION IS FOR THE BIRDS

Will this costly new rule produce net benefits?

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Animals eat a lot of disgusting things, yet they often suffer little harm from doing so. But the U.S. Food and Drug Administration now seeks to extend its regulatory reach to protect Lassie, Mister Ed, and maybe even Lamb Chop from hazards in manufactured animal food.

The Food Safety Modernization Act, signed in 2011, directs the FDA to adopt regulations requiring facilities that manufacture, process, pack, or hold food—including animal food—to implement preventive controls to ensure that the food is not “adulterated.” Last October, the FDA proposed a regulation to implement that mandate for both pet food and livestock feed.

The proposed regulation contains two principal requirements: First, most animal food manufacturing facilities must implement a set of “current good manufacturing practices” intended to prevent contamination of animal food. Second, those facilities must develop a written food safety plan, conduct a hazard analysis, implement preventive controls for hazards that are reasonably likely to occur, monitor the controls, verify that they are effective, take any corrective actions, and maintain records on all of those efforts. That is, the facilities must implement a Hazard Analysis and Critical Control Points (HACCP) system.

The proposed regulation does establish criteria to exempt certain “qualified facilities” and activities from the costly second requirement. The FDA sought comment on the dollar threshold to use in defining “very small” businesses that would be given that exemption.

Unfortunately, the Regulatory Impact Analysis (RIA) accompanying the proposed regulation provides scant assessment of the

nature, cause, and significance of the animal food problem the regulation seeks to solve. In the absence of such an assessment, the RIA has no basis for estimating the benefits of the proposed rule or the benefits associated with the alternative definitions of “very small” business. It estimates the costs of the alternatives, but since the differential benefits of the alternatives are unknown, there is no way to determine whether the more restrictive definitions of “small business” produce benefits that justify the additional costs.

Indeed, the RIA fails to prove that the regulation would produce any significant benefits at all. Our own estimate of the monetized benefits suggests that the proposed rule’s costs—as estimated by the FDA—of between \$87 million and \$129 million annually substantially outweigh our best estimate of \$17 million in annual benefits.

WHAT'S THE PROBLEM?

The very first principle of regulation enunciated in Bill Clinton’s still-operational Executive Order 12866 governing regulatory analysis and review is that “each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.” To accurately identify the problem at hand, the FDA should have explained why marketplace incentives are inadequate to produce the optimal level of animal food safety and presented evidence that its explanation is sound. To assess the significance of the problem, the FDA should have demonstrated that the problem is large and widespread, not just the consequence of a few bad actors or a few anecdotal problems in the marketplace.

Instead, the RIA merely hypothesizes that producers and



consumers may not have sufficient information about the safety attributes of animal foods. It suggests that neither legal liability nor product branding may be sufficient to produce the optimal level of food safety. The section of the RIA titled “Need for Regulation” does suggest that market failure could be the cause of this hypothesized problem. To its credit, the RIA consistently states that safety “may” be below the optimal level and that government regulation of food safety “may” be able to improve social welfare. However, the section presents no evidence about the actual state of consumers’ or producers’ knowledge about animal food quality or contamination, no evidence about the effectiveness of the

legal system or branding in promoting animal food safety, and no information about how much the safety of animal food deviates from the optimal level. In fact, given the relatively small number of incidents of tainted animal food that the FDA cites, it is entirely possible that safety is currently at the optimal level.

Some of the hazard and recall information the FDA presents actually undermines the argument that the proposed regulation would solve a significant problem that is not already addressed by marketplace incentives and legal liability. The RIA offers three figures showing that animal food recalls can be costly to manufacturers: In 2008, a pet food company paid \$3.1 million to settle a

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lawsuit stemming from aflatoxin contamination. The largest-ever pet food recall cost the industry more than \$50 million; in its wake, demand for pet foods not affected by the recall increased, suggesting that consumers penalize firms that produce unsafe food and reward those that produce safe food. The RIA also estimates that animal feed recalls cost the industry approximately \$32.6 million annually in direct product losses. Such figures suggest that the marketplace creates substantial incentives for the industry to keep animal food safe.

“Nevertheless,” the analysis concludes, “animal food recalls continue to occur, suggesting that market incentives are not sufficient to motivate manufacturers and others processing and handling animal food to adequately control hazards that can cause recalls.” This statement is a non sequitur. It is equivalent to

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claiming that the optimal level of risk is zero, which implies that pet and livestock owners (or perhaps our broader society) would be willing to pay an infinite amount to eliminate the last little bit of risk of animal food contamination so that there would be zero recalls. The RIA presents no evidence to demonstrate that this implausible assumption is true.

The fact that some recalls occur does not prove that a market failure exists. The FDA articulated a market failure that is theoretically possible, but it did not demonstrate that the market failure actually exists.

Significance not demonstrated / The closest thing to evidence of a widespread adulteration problem the RIA provides is a recitation of statistics and examples of hazards found in animal food, human illnesses traced to salmonella contamination in animal food, and animal food recalls. At most, this information proves that mistakes do happen and sometimes hazards turn up in animal food. The statistics on hazard incidents and recalls are presented without any contextual information showing whether they are frequent or infrequent, or what percentage of the market they constitute. As a result, it is impossible to conclude from the RIA whether adulteration of animal food is a large or widespread problem.

Statistics in the RIA reveal that the majority of pet food recalls in recent years resulted from one event: the economically motivated decision of two Chinese companies to intentionally add

melamine to pet food ingredients that were shipped to the United States. This one incident accounted for more than 60 percent of all Class I pet food recalls and 80 percent of recalls for chemical contamination between 2006 and 2010. Given that one such instance accounts for the majority of pet food recalls, it's quite possible that a much more limited regulation, inspection, or enforcement initiative targeted at bad actors could eliminate most of the adulteration problem without forcing an entire industry to adopt costly new procedures. The presence of a few bad actors in a market is not the same thing as a widespread market failure. Alternatively, it may be that the Chinese manufacturers did not know that melamine was a problem. If not, the remedy would be for the FDA to produce better information to inform manufacturers about what is and is not acceptable as an ingredient in pet food.

Another significant portion of reported hazards consists of salmonella present in animal food. The largest number of animal food hazards submitted to the Reportable Food Registry between 2009 and 2011 involved salmonella, which accounts for 21 of the 47 reports in those years. Between 2006 and 2010, salmonella led to the second-highest number of pet food recalls after melamine, accounting for 17 percent of all Class I pet food recalls. The RIA reports that in most cases, human infection

occurred because of improper handling (hand-to-mouth contact) of contaminated dry pet food or frozen mice intended as reptile food.

The real culprit here is not the absence of regulation, but rather improper handling of animal food by consumers. In its report on a major salmonella incident linked to pet food, the Centers for Disease Control and Prevention (CDC) noted,

To prevent Salmonella infections, persons should wash their hands for at least 20 seconds with warm water and soap immediately after handling dry pet foods, pet treats, and pet supplements, and especially before preparing and eating food for humans. Infants should be kept away from pet feeding areas. Children younger than 5 years old should not be allowed to touch or eat dry pet food, treats, or supplements.

The FDA should at least have assessed whether a much less restrictive approach, such as a parental education campaign or mandatory warning labels containing the CDC's advice, could effectively reduce salmonella-related illnesses.

WHERE ARE THE BENEFITS?

The FDA usually estimates benefits for its regulations by first estimating the maximum total number of cases of illness associated with the products covered by the regulation. Then it translates that number of illnesses into monetary terms. Finally, it

multiplies that maximum monetary amount by its estimate of the effectiveness of the regulation at preventing illness.

The FDA stated that it does not have enough information to estimate the benefits of the proposed regulation. The necessary information for such an estimate includes the number of cases of human and animal illness associated with animal food that the regulation would prevent and the value of those cases of illness. Estimating the total number of cases and, in some instances, the effectiveness of various options at reducing those cases is a risk assessment. Yet, the FDA chose not to perform a quantitative risk assessment for this rule.

Data do exist to make some reasonable estimates of the maximum total number of illnesses associated with animal food and the monetary value of those illnesses. However, those data do not appear to justify the FDA's regulatory conclusions.

In the RIA, the FDA named four potential benefits of the regulation:

- reduced risk of adverse health effects to humans from handling contaminated animal food
- reduced risk of serious illness and death to animals
- reduced risk of humans consuming food derived from animals that consumed contaminated food
- reduced risk of product recalls

We address those risks below.

Reduced risk to humans/ In the RIA, the FDA states, "Salmonella, the most commonly identified biological hazard in animal foods, primarily affects humans that handle contaminated animal food." Data from the CDC allow us to estimate the maximum possible number of those cases that may be due to animal food.

The CDC estimates that there are just over 1 million human cases of salmonellosis in the United States every year associated with domestic food consumption. Some 94 percent of those cases are related to human food consumption. Therefore, using CDC data, we can calculate that there are roughly 65,500 human cases of salmonellosis in the United States every year that are not travel-related and are not related to human-food consumption.

According to the CDC, human non-foodborne salmonellosis outbreaks have been associated with handling home-kept birds and reptiles (not handling their food), microbiological laboratories, and human contact with pet food. Human-to-human transmission at daycare facilities has also been

reported on several occasions. Table 1 shows recent incidents of human non-foodborne salmonellosis outbreaks reported by the CDC on its website. The CDC does not necessarily post all outbreaks of the disease; however, since the FDA does not claim that any other outbreaks related to animal food exist, it is reasonable to believe that all known outbreaks associated with animal food are reported on the CDC website and shown in Table 1.

Over a seven-year period, the CDC reports a total of 1,910 laboratory-confirmed cases of human non-foodborne salmonellosis in the United States, which averages to about 275 laboratory-confirmed cases per year. That is very far from the 65,500 annual non-foodborne domestic cases of salmonellosis implied by the CDC data discussed above. The Table 1 data are strongly suggestive of the relative frequencies of sources of salmonellosis outbreaks. Nine of the 13 outbreaks and 87 percent of the laboratory-confirmed cases reported over the seven-year period by the CDC are related to infected pets and animals kept at home. Only three of the 13 outbreaks and only 8 percent of the laboratory-confirmed cases reported during the period are related to animal food. All of those cases are related to pet food; none are related to feed for livestock.

The one remaining outbreak reported by the CDC during the period puts the human health hazard from animal food in context. Some 6 percent of the laboratory-confirmed non-foodborne salmonellosis cases were associated with salmonellosis contracted from microbiological laboratories. In other words, microbiological laboratories are only slightly less hazardous as a cause of salmonellosis than pet food. The CDC data show that only 8 percent of the total annual non-foodborne domestic cases of salmonellosis, or about 5,000 cases, are related to pet food.

In analyses of other recent regulations, the FDA has published its estimate of the value of an average case of foodborne salmonellosis at \$4,622. Therefore, using CDC and FDA information, we find that the monetary value of the maximum possible number of cases of human illness associated with animal food is about \$23 million. Further, the FDA cannot claim the entire \$23 million as the benefits of the regulation for preventing human illness associated with salmonella in animal food without evidence that the regulation will eliminate all cases of human non-foodborne salmonellosis associated with pet food.

Serious illness and death to animals/ In the RIA, the FDA states, "Chemical

TABLE 1
HUMAN NON-FOODBORNE
SALMONELLOSIS OUTBREAKS

YEAR	LABORATORY-CONFIRMED CASES	SOURCE
2007	62	pet food
2010	241	water frogs
2010	34	frozen rodents
2011	109	microbiological laboratories
2011	68	chicks and ducklings
2012	473	small turtles
2012	49	dry dog food
2012	195	live home-kept poultry
2012	93	live home-kept poultry
2012	46	live home-kept poultry
2012	26	pet hedgehogs
2013	158	live home-kept poultry
2013	356	live home-kept poultry

NOTE: Shaded rows indicate forms of pet food

SOURCE: Centers for Disease Control, "Reports of Selected Salmonella Outbreak Investigations," <http://www.cdc.gov/salmonella/outbreaks.html>.

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contamination of animal food with aflatoxins or melamine creates a risk of adverse health effects for the animals that consume the contaminated food.” And “formulation or mixing errors can cause nutrient imbalances in animal food that could pose a serious health risk to animals. Foreign substances such as metal, glass, or plastic fragments are types of physical hazards found in animal food.”

It is difficult to estimate the number of serious illnesses and deaths of animals related to animal food. But a rough estimate can be made relying on the information described by the FDA in the preamble to the proposed rule. In the five years between 2008 and 2012, more than 2,500 consumer complaints (about 500 per year) were called in to the FDA’s district offices regarding animal food for pets and livestock. In the four years that the Reportable Food Registry has operated, 71 reports (about 20 per year) have been related to animal food. In the three years that the FDA’s Safety Reporting Portal has been in operation, more than 2,900

It’s odd that the FDA claims its proposed regulation will prevent human illness, given that all categories of human food of animal origin are already under federal preventive control regulations or proposed regulations.

consumer complaints (about 970 per year) were related to pet food. If we assume that all of those reports and complaints are accurate, and that none of them related to the same incident with the same animal, and that one animal is involved in each report, then there are, on average, reports of about 1,500 animals made sick annually from the food that they ate.

Self-reporting is notoriously inaccurate, and people motivated to complain in one forum are likely to lodge the same complaint multiple times in multiple forums, so those factors weigh in the direction of 1,500 being an overestimation. However, multiple animals could be involved with any individual complaint, and there are likely to be unreported events. If we assume that taking all of those factors into consideration causes the total number of annual FDA reports to be only a third of the actual number of animals sickened by food per year, then the average number of animals sickened by food annually is about 4,500.

A survey conducted in April 2010 gives information on pet owners’ willingness to pay for saving a sick pet. Some 22 percent of responding pet owners were willing to pay \$5,000 to save their pet. The percentages increased as the cost declined: 35 percent were willing to pay \$2,000, 42 percent would pay \$1,000, and 62 percent were willing to pay \$500. A weighted average of those responses gives a willingness to pay to save a sick pet of \$1,530

(\$1,608 in 2013 dollars). That estimate is not based on actual expenditures on veterinary services. The poll is very similar to a stated preference survey used to measure consumer willingness to pay for nonmarket goods. Reported willingness to pay was not affected by respondents’ income, a preferred characteristic of willingness-to-pay results.

Multiplying a willingness to pay to save a sick pet of \$1,608 by 4,500 sick animals per year yields an estimated monetized benefit of about \$7.25 million per year that the regulation could claim for saving sick animals.

Humans consuming animals/ In the RIA, the FDA states, “Humans may be exposed to pesticide residues or aflatoxins when they eat food from animals fed contaminated feed.” In reality, the proposed regulation is unlikely to create any benefits from reducing that type of exposure.

The FDA can claim no additional benefit for this proposed regulation from reduced exposure to pesticide residues because there are already ample federal regulations in place to control pesticide contamination of food. The U.S. Department of Agriculture has consistently reported that pesticide residues in food (and especially in food from animals) do not pose a safety risk to humans. In 2011, the most recent year for which data are available, the Pesticide Data Program (PDP) tested 371 egg samples and 743 milk samples. Only two egg samples and no milk samples were found to be in violation of U.S. pesticide regulations. According to the USDA, “the 2011 PDP report confirms that overall pesticide chemical residues found on the foods tested are at levels below the tolerances established by the Environmental Protection Agency and do not pose a safety concern.” In the same press release, the EPA states, “The newest data from the PDP program confirm that pesticide residues in food do not pose a safety concern for Americans.”

The FDA also cannot claim that the proposed regulation would reduce human exposure to aflatoxin because aflatoxin contamination of meat is very rare. There have been no producer recalls or enforcement actions by the Food Safety and Inspection Service (FSIS) or the FDA relating to aflatoxin in meat, poultry, eggs, seafood, or dairy products in recent years.

Indeed, this is an odd category of benefits for the FDA to claim, given that all categories of human food of animal origin are already under federal preventive control regulations, or such regulations have recently been proposed. If there were benefits to humans from reduced exposure to pesticide residues or aflatoxins in food of animal origin, those benefits would have been counted by the FSIS and the FDA. Neither agency did so.

Risk of recalls/ The FDA repeatedly claims in its RIA that another

benefit of the proposed regulation is a reduction in the number of recalls of animal food. However, the FDA offers no evidence to support that assertion. Indeed, the evidence appears to prove the opposite: more regulation leads to more recalls, not fewer.

To appreciate this, consider the FSIS Pathogen Reduction HACCP Systems Final Rule, intended to combat salmonella and other pathogen contamination at meat and poultry slaughterhouses and processing facilities. The rule became effective for producers with 500 or more employees in January 1998, for producers with 10–499 employees in January 1999, and for producers with fewer than 10 employees or sales of less than \$2.5 million in January 2000. The regulation is a preventive-controls type of regulation, similar in many ways to the FDA's proposed regulations for human and animal food. Figure 1 shows the number of meat and poultry recalls reported on the FSIS website.

Between 1994 and 1997, the average annual number of recalls resulting from contamination at slaughterhouses and processing plants was less than 36. Since 1998 the average annual number has exceeded 70. In only one year since implementation of the regulation (2006) has the annual number of recalls been close to the average number of recalls before implementation. If reduced recalls would be a benefit of regulation, then increased recalls would be a cost. Based on the evidence, the FDA should expect that its pet food regulation will increase costs both to industry for dealing with more recalls and to government for investigating more recalls. As far as FDA-regulated foods are concerned, there doesn't seem to be a successful track record to point to.

If the FDA believes that fewer recalls are unambiguously better than more recalls, then it needs to explain how its regulation for animal food differs from the FSIS regulation for human food in a way that will lead to fewer recalls. It also needs to explain why it is better to have a new regulatory system for animal food that

results in fewer recalls than before, but a new regulatory system for human food that has more recalls than before.

EFFECTIVENESS OF THE REGULATION

The only way for the proposed regulation to reduce risk to humans, pets, or farm animals is for it to change producer behavior in such a way that humans or animals are harmed less frequently than they would be without the regulation. Although the RIA provides no evidence that the current level of animal food safety is suboptimal, it asserts with certainty that the regulation will produce benefits:

The benefits of the proposed rule would result from fewer incidents of adulterated animal food ingredients and adulterated finished animal food products. Better management of hazards in animal food during manufacturing, distribution, storage and handling would reduce the likelihood that adulterated animal food could reach the market. Reducing the adulterated animal food incidents would (1) reduce the risk of serious illness and death to animals, (2) reduce the risk of adverse health effects to humans handling contaminated animal food, and (3) reduce the risk of consuming human food derived from animals that consumed contaminated food.

Similar assertions without evidence occur repeatedly in the RIA. The apparent assumption is that the regulations will reduce adulteration because they are intended to reduce adulteration. The FDA offers no evidence on the effectiveness of the proposed regulatory controls at reducing contamination. Since no empirical evidence is presented, it is impossible to tell from the RIA whether, or by how much, the regulation would reduce the risk of adulteration.

The absence of empirical evidence is particularly striking when one realizes that the FDA has experience with similar regulations in other contexts. The Notice of Proposed Rulemaking (NPRM) notes that in the past, the FDA developed current good manufacturing practices for human food and required seafood and juice processors to implement HACCP. In fact, the FDA tentatively concluded that current good manufacturing practices for human food are the appropriate starting point for developing similar practices for animal food. The USDA has mandated HACCP for meat and poultry processors. The NPRM asserts that "these efforts have contributed to progress on food safety," but neither the NPRM nor the RIA cites any retrospective studies that demonstrate this. Retrospective analysis of the regulatory initiatives

FIGURE 1
RECALLS UNDER FSIS PATHOGEN REDUCTION HACCP SYSTEM RULES



Source: USDA, Food Safety and Inspection Service, "Recall Case Archive"

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could determine whether the regulations reduced contamination of human food, and by how much. Such information would at least provide some analogous evidence that would help the FDA assess the effectiveness of the proposed rules for animal food.

In fact, the FDA notes early in the document that it has previously required HACCP in other contexts. Prior FDA examples do not inspire confidence in the proposed animal food rule.

The first FDA HACCP rule governed seafood handling. The FDA has never evaluated that rule's effectiveness, but available data raise questions about its effectiveness. For example, in its RIA, the FDA estimated that about half of the benefits of the seafood rule would come from reducing *vibrio Vulnificus* from 60 cases per year to between 30 and 48 cases per year. In 2011, the CDC reported that there were 113 cases.

The FDA also cites its juice HACCP rule. Virtually the entire problem addressed by the rule was caused by the fact that, at the time, apples were pressed into juice and went to market unpasteurized. That problem was solved by pasteurization, not the complicated recordkeeping associated with HACCP.

Current concerns about jerky treats for pets illustrate why it is invalid to simply assume that enacting a regulation will eliminate a risk. The FDA notes on its website,

Since 2007, FDA has received reports of illnesses in pets associated with the consumption of jerky pet treats. As of September 24, 2013, FDA has received approximately 3,000 reports of pet illnesses (on average about 430 reports per year or about 30 percent of the reports made to the FDA) which may be related to consumption of the jerky treats.

The FDA has investigated numerous jerky facilities and products. The FDA has tested for numerous biological, chemical, physical, and radiological hazards. To date, no one—including the FDA—knows what is in the jerky treats that is making pets sick. If the FDA and jerky-treat manufacturers are unable to identify the problem and prevent it, then there is no reason to believe that the proposed regulation would prevent that kind of problem from occurring.

And even if the jerky-treat problem is solved, there are likely to be similar problems in the future that the regulation cannot prevent. Products do not magically get better because more regulations cover them. So the regulation is almost certain to fail to prevent at least 30 percent of the animal illnesses even if the provisions of the regulation are completely effective at preventing hazards of known causes. And that is a big “if” because the FDA has no evidence that any of the provisions of the proposed regulation will be effective at all.

Potential range of benefits/ Adding together the estimates of the

monetary value of the human- and animal-health risks associated with animal food gives us the maximum possible benefit that the regulation could claim. We calculate that to be just over \$30 million per year. Since the FDA presents no evidence that the regulation will be effective, the benefits could be as low as \$0.

The FDA estimated that its proposed preventive controls regulation for human food would be 56 percent effective at preventing illness associated with fruits and vegetables. The FDA has pre-

If the FDA and jerky-treat manufacturers are unable to identify the problem and prevent it, then there is no reason to believe that the proposed regulation would prevent that kind of problem from occurring.

sented almost no data to support that estimate and likewise has offered no evidence for the effectiveness of the proposed animal food regulation. However, if we make the generous and convenient assumption that the proposed animal food regulation will be equally effective as the FDA claimed the human-food proposed regulation will be, then the estimated annual benefits from the animal feed rule would be about \$16.9 million.

NET BENEFITS AND ALTERNATIVES

Our estimation of benefits allows us to show the estimated net benefits for the proposed regulation and for some viable regulatory alternatives.

Net benefits/ The FDA estimates that the proposed rule will cost between \$87 million and \$129 million per year, not counting about \$17 million in additional costs from other regulatory options that the FDA may add to the final rule. Those costs are just compliance costs to the industry, not overall costs to society. Nevertheless, the costs substantially exceed the benefits for all of the alternatives the FDA considered.

We offer no opinion on whether the compliance costs to industry are accurately estimated. However, we suspect the estimate understates the overall cost to society. If the FDA were to go forward with this particular rule, it opens up the possibility of doing more harm than good. Based on the size of the market, it appears that manufacturers—however they are doing it—already have the food safety problem very much in control. As we pointed out earlier, there does not seem to be a large number of problems that the FDA is attempting to address with this complex rule requiring a lot of additional activity on the part of manufacturers. Given that it is mandating entirely new activities, those activities

will almost certainly supplant some of the existing food-safety controls, which appear to be effective. In other words, the FDA may be requiring ineffective activities that will replace effective activities. This could make animal feed less safe. It is certainly plausible, given that the FDA has no evidence that the activities required under the rule will produce safer food.

The RIA presents annualized costs, but that is only one way to present costs. Another is to discount all future costs back to today to show how much money would have to be invested to pay those costs in the future. Depending on the discount rate (we use the standard 7 percent and 3 percent rates), the total discounted cost is \$6.7–\$15.7 billion. No matter how you think about it, that is a substantial sum to be spending on an unproven rule. Much of the cost is likely to be passed on to consumers in the form of higher prices. With benefits no greater than \$16.9 million annually, the problem the regulation seeks to address is just not big enough to warrant such a costly regulation.

Net benefits of alternatives/ The proposed rule notes that there are different options for applying the regulation to very small businesses. Each option results in a different estimated cost and benefit. To calculate the benefits for each definition of “very small” business, we assume that benefits are proportional to the percent of industry output produced by businesses that do not fit the definition of “very small.” Depending on the definition of “very small,” benefits range from \$13.4 million to \$16.9 million annually, with costs between \$86.9 and \$128.8 million annually. Under any definition of “very small” business, the costs of the regulation substantially outweigh the benefits.

The FDA has also foreshadowed that it may add several additional provisions to the final regulation. Adding the \$17.04 million annual cost of the additional provisions makes the net benefits even more negative than the main regulatory proposal.

Based on the information available relating to the hazards associated with animal food, another obvious option is to issue a regulation that only covers pet food and not livestock feed. A pet-food-only rule would apply to about 6–7 percent of animal food manufacturing facilities, but it would achieve almost all of the benefits of the regulation covering all facilities. We estimate that the benefits of a regulation restricted to pet food would total \$11.8–\$14.9 million annually. Since no data indicate that non-pet animal food has been related to human salmonellosis, a pet-food-only rule would achieve all of the human health benefits.

The FDA does not provide information on how many of the reports and complaints about animal food are related to pets or non-pets, so we assume that the reports and the animal health benefits are divided equally between pet food and non-pet food. We assume that pet food facilities have compliance costs similar to non-pet food facilities, so that the only difference is in the number of facilities covered. We also assume that the number of ingredient suppliers covered under a pet-food-only regulation is the same as for the proposed regulation and that the number

of foreign facilities covered is proportional to the number of domestic facilities covered.

Restricting the regulation to pet food significantly lowers the cost to between \$5.9 million and \$8.6 million annually. The benefits of the rule might even exceed the costs if the rule is restricted to pet food. We say “might” because we have not attempted to independently verify the FDA’s cost estimates and because we are only guessing at the effectiveness of the regulation, since the FDA has provided no data to show that the regulation will be effective.

CONCLUSION

The absence of empirical analysis of the nature of the problem, the significance of the problem, and the benefits of the regulation deprive commenters and the public of critical information they need to comment intelligently on the proposed regulation. The absence of empirical analysis also deprives Congress of information it may find useful if it decides to reconsider this regulation under the Congressional Review Act or to revisit the provision of the Food Safety Modernization Act that requires it. We have estimated the potential benefits of the regulation, and we find that the FDA’s estimate of costs for the proposed regulation substantially exceeds the maximum potential benefits the regulation could conceivably produce.

There are a lot of things the FDA could have done differently. Among them:

- Use empirical evidence to evaluate whether a market failure exists. A market failure exists if the level of animal food safety expected in the future is likely to depart from the optimal level because consumers and producers lack sufficient information to detect and deter hazards.
- Assess whether a more limited regulation, inspection, or enforcement initiative targeting bad actors in the marketplace could accomplish many of the goals of the Food Safety Modernization Act more effectively or at lower cost than the proposed regulation.
- Assess whether emphasizing tracebacks and attribution might not create sufficient incentive for manufacturers to exercise due diligence.
- Assess whether a less-intrusive labeling regulation or public education campaign could reduce the incidence of salmonella infection from animal food more effectively or at a lower cost than the proposed regulation.
- Assess whether a regulation targeted at pet food only could achieve most of the goals of the proposed regulation at lower cost.
- Demonstrate with empirical evidence that any new regulation is likely to produce significant, quantifiable benefits by reducing the risk of hazards below the level that is likely to occur in the absence of a new regulation.

In the absence of that information, the proposed animal food regulation looks like a dog. R