MERCATUS CENTER
George Mason University
Bridging the gap between academic ideas and real-world problems

PUBLIC INTEREST COMMENT

CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

JERRY ELLIG AND RICHARD WILLIAMS

Food and Drug Administration, HHS
Comment period closes March 31, 2014
Comment submitted March 4, 2014

INTRODUCTION

The Regulatory Studies Program of the Mercatus Center at George Mason University is dedicated to advancing knowledge about the impact of regulation on society. As part of its mission, the program conducts careful and independent analyses that employ contemporary economic scholarship to assess rulemaking proposals and their effects on the economic opportunities and the social well-being available to of all members of American society.

This comment addresses the efficiency and efficacy of this rule from an economic point of view. Specifically, it examines how the rule may be improved by more closely examining the societal goals the rule intends to achieve and whether this proposed regulation will successfully achieve those goals. In many instances, regulations can be substantially improved by choosing more effective regulatory options or more carefully assessing the actual societal problem.

SUMMARY

The Food Safety Modernization Act, signed in 2011, directs the Food and Drug Administration (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," as defined in section 402 of the Food, Drug, and Cosmetic Act.[1] The proposed regulation applies both to pet food and to livestock feed, and it contains two principal requirements. First, it requires that facilities implement a set of "current good manufacturing practices" (CGMPs) intended to prevent contamination of animal food.[2] Second, it requires covered facilities to 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 corrective actions, and maintain records.[3]

1. Department of Health and Human Services, Food and Drug Administration, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals," 78 Fed. Reg. 209 (October 29, 2013), 64736–837. (Hereafter referred to as "NPRM.")
2. Id.
3. Id.

For more information, contact
Robin Bowen, (703) 993-8582, rbowen@mercatus.gmu.edu
Mercatus Center at George Mason University
3434 Washington Boulevard, 4th Floor, Arlington, VA 22201

The proposed regulation also establishes criteria that exempt certain "qualified facilities" and activities from the requirement for hazard analysis and risk-based preventive controls. Particularly noteworthy are proposed exemptions for "small" businesses (average annual sales below $500,000 and at least half of sales to consumers or local retailers or restaurants), "small" businesses performing on-farm activities (fewer than 500 employees), or "very small" businesses (total annual sales below a threshold to be determined by the FDA). The FDA seeks comment on the dollar threshold to use in defining "very small" businesses.[4]

Unfortunately, the Regulatory Impact Analysis (RIA) accompanying the proposed regulation provides scant assessment of the nature, cause, and significance of the 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 analysis fails to prove that the regulation would produce any significant benefits at all. Our own estimate of the benefits suggests that the costs of the proposed rule estimated by the FDA ($87–129 million annually) substantially outweigh any possible benefits (about $30 million per year).

Before issuing a final regulation, the FDA should:

- 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 or 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 create sufficient incentive for manufacturers to exercise due diligence.[5]
- 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.
- Assesses whether a regulation targeted only at pet food 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.

IDENTIFICATION OF THE PROBLEM

The very first principle of regulation enunciated in Executive Order 12866 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."[6] To accurately identify the problem at hand, the FDA should explain why marketplace incentives are inadequate to produce the optimal level of animal food safety and present evidence that this explanation is true. To assess the significance of the problem, the FDA should demonstrate that the problem is large and widespread, not just the consequence of a few bad actors or a few anecdotal problems in the marketplace.

4. Id.
5. Richard A. Williams, "A New Role for the FDA in Food Safety" (Working Paper No. 10-69, Mercatus Center at George Mason University, Arlington, VA, November 2010), http://mercatus.org/publication/new-role-fda-food-safety.
6. Exec. Order No. 12866, 58 Fed. Reg. 190 (October 4, 1993), Sec. 1(b)(1).

No evidence of market failure presented

The RIA hypothesizes that producers and consumers may not have sufficient information about the safety attributes of animal foods. As a result, it suggests that neither legal liability nor product branding may be sufficient to produce the optimal level of food safety. To its credit, the section of the RIA titled "Need for Regulation" merely presents market failure as a possibility. It consistently states that safety "may" be below the optimal level and that government regulation of food safety "may" be able to improve social welfare.[7]

Such hedging is appropriate because this 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 minimal number of events that the FDA presents, it is entirely possible that it is at the optimal level.

Some of the hazard and recall information the FDA presents actually undermines the argument that the regulation would solve a significant problem that is not already addressed by marketplace incentives and legal liability. The RIA presents three figures suggesting that animal food recalls can be costly to manufacturers. In 2008, a pet food company paid $3.1 million to settle a lawsuit stemming from contamination of food with aflatoxin.[8] The largest-ever pet food recall cost the industry more than $50 million.[9] 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.[10] The RIA also estimates that animal feed recalls cost the industry approximately $32.6 million annually in direct product losses.[11] Such figures suggest that the marketplace creates substantial incentives for the industry to keep animal food safe. The RIA itself notes that the direct cost of recalls and loss of customer goodwill provide incentives for manufacturers to reduce risks.[12] Also, all of these costs to industry are significantly lower than the FDA's estimate of the annual cost of the regulation.

"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."[13] This statement is a non sequitur. The assertion is equivalent to 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.

In short, the FDA has articulated a market failure that is theoretically possible, but it has not demonstrated that the market failure actually exists.

Significance of the problem 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.[14] 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.

---

7. Department of Health and Human Services, Food and Drug Administration, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, Preliminary Regulatory Impact Analysis" (undated, available in the docket at regulations .gov), 11–12. (Hereafter referred to as "RIA.")
8. Id., 18.
9. Id., 19.
10. Id., 19.
11. Id., 21.
12. Id., 17.
13. Id., 17.
14. Id., 14–24.

Statistics in the RIA reveal that the majority of animal 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.[15] 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.[16] The NPRM explicitly seeks comment on whether the FDA should "include potential hazards that may be intentionally introduced for economic reasons."[17] Given that one such instance accounts for the majority of pet food recalls, the FDA would do well to consider whether 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.[18] 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.[19] 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.[20]

The real culprit here is not the absence of a regulation mandating CGMP and HACCP, 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 note, "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 aged <5 years should not be allowed to touch or eat dry pet food, treats, or supplements."[21] 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.[22]

ANALYSIS OF BENEFITS

The FDA states that it does not have enough information to estimate the benefits of the proposed regulation. The information that would be needed to estimate benefits for a regulation is 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. The FDA usually estimates benefits for its regulations by first estimating the maximum total number of cases of illness that are 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. Estimating the total number of cases and, in some instances, the effectiveness of various options at reducing those cases, is a risk assessment. The Food Safety and Modernization Act continually refers to risk analysis to make decisions, and as the FDA correctly notes, risk analysis is composed of risk assessment, risk communication and risk management. In fact, the FDA notes that "the use of risk concepts is not new for the Agency, as FDA routinely tries to estimate public health impact in deciding where to focus regulatory effort

15. NPRM, 64746.
16. RIA, 17.
17. NPRM, 64745.
18. RIA, 15.
19. Id., 17.
20. Id., 22–23.
21. Centers for Disease Control, "Update: Recall of Dry Dog and Cat Food Products Associated with Human Salmonella Schwarzengrund Infections—United States, 2008," *MMWR Weekly* (November 7, 2008).
22. A bag of dog food in the author's garage has no such warning label. I washed my hands anyway after checking it before returning to the computer.

in general."[23] Nevertheless, the FDA has chosen not to perform a quantitative risk assessment for this rule despite the obvious value it would have in informing decisions.

The FDA could follow its customary benefit-estimation process, including a risk assessment, for this regulation. The problem is not that there are no data, but that the data do not justify the FDA's regulatory conclusion. The 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. Our comment makes those estimates and also estimates net benefits for some obvious regulatory alternatives not considered by the FDA. By saying that it does not have enough information to estimate benefits for the proposed rule, the FDA seems to be blaming the economic analysis of the regulation. However, it is clear that the real problem is that the regulation was designed and written without making use of the insights of a sound economic analysis.

In the RIA, the FDA names four potential benefits of the regulation: (1) reduced risk of adverse health effects to humans handling contaminated animal food, (2) reduced risk of serious illness and death to animals, (3) reduced risk of humans consuming food derived from animals that consumed contaminated food, and (4) reduced risk of product recalls.[24] We will address these risks in turn.

1. Reduced risk of adverse health effects to humans handling contaminated animal food

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 Centers for Disease Control and Prevention (CDC) allow us to estimate the maximum possible number of these cases that may be due to animal food.

The CDC estimates that there are 1,027,561 human cases of salmonellosis in the United States every year associated with domestic food consumption. According to the CDC, 94 percent of salmonellosis cases in the United States are related to human food consumption.[25] Therefore, using CDC data, we can calculate that there are an estimated 65,589 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 cases of salmonellosis are associated with a variety of vectors. In the last several years, 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.[26] Human-to-human transmission at daycare facilities has also been reported on several occasions. Table 1 below shows human non-foodborne salmonellosis outbreaks reported by the CDC on its website. The CDC does not post all outbreaks on its website; 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.

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, or on average about 273 laboratory-confirmed cases per year. That number of cases is very far from the estimated 65,589 annual non-foodborne domestic cases of salmonellosis. But the 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 eight 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.

---

23. Animal Food Rule, 78 Fed. Reg. 209 (October 29, 2013) 64740.
24. RIA, 13.
25. Elaine Scallan et al., "Foodborne illness acquired in the United States—major pathogens," *Emerging Infectious Diseases* 17, no. 1 (January 2011): 11, http://wwwnc.cdc.gov/eid/article/17/1/pdfs/p1-1101.pdf.
26. CDC, Reports of Selected Salmonella Outbreak Investigations, last modified January 14, 2014, http://www.cdc.gov/salmonella/outbreaks.html.

Table 1. Human non-foodborne salmonellosis outbreaks reported by CDC (color-coded by source type)

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

Source: CDC, Reports of Selected Salmonella Outbreak Investigations, http://www.cdc.gov/salmonella/outbreaks.html.

The one remaining outbreak reported by the CDC during this period puts the human-health hazard related to animal food in context. Six percent of the laboratory-confirmed non-foodborne salmonellosis cases were associated with salmonellosis contracted from microbiological laboratories. Microbiological laboratories are only slightly less hazardous as a vector for causing salmonellosis than pet food. These CDC data show that only eight percent of the total annual non-foodborne domestic cases of salmonellosis, or about 4,979 cases, are related to pet food. This information from the CDC allows us to estimate the maximum possible number of cases of human illness that are associated with the products covered by the proposed regulation.

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.[27] 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 $23,014,000.

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.

2. Reduced risk of serious illness and death to animals

In the RIA, the FDA states, "Chemical contamination of animal food with aflatoxins or melamine creates a risk of adverse health effects for the animals that consume the contaminated food."[28] 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."[29]

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

27. FDA, "Analysis of Economic Impacts: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption," 2013, 67, http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf. The value of an average case is an estimate of the medical costs and the pain and suffering that accompany a case of salmonellosis. The benefits of the rule then would be reducing cases valued at this amount.
28. RIA, 14.
29. Id., 14.

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 consumer complaints (about 970 per year) related to pet food were lodged. If we assume that all of these 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 sick annually from the food that they ate.

Self-reporting is notoriously inaccurate, and people motivated to complain in one forum are very likely to lodge the same complaint multiple times in multiple forums, so those factors weigh in the direction of that 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 these 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 number of animals sickened by food per year is on average about 4,500.

The FDA states that it does not have enough information to estimate the willingness of consumers to pay for safer pet food. But some information is available. A survey conducted in April 2010 gives information on pet owners' willingness to pay for saving a sick pet.[30] Twenty-two percent of responding pet owners were willing to pay $5,000 to save a sick pet. The percentages increased as the cost declined. Thirty-five percent were willing to pay $2,000, 42 percent would pay $1,000, and 62 percent of responding pet owners were willing to pay $500 to save a sick pet. A weighted average of those responses gives a willingness to pay to save a sick pet of $1,530 (or $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. If the FDA does not accept these results, then it should explain how it would reach a higher estimate.

Another survey provides information on the median survey respondent's relative value for farm animals compared to humans.[31] Respondents valued the suffering of 11,500 farm animals as equivalent to the suffering of one human. The FDA has recently used $7.9 million as the value of a statistical human life.[32] Using that value and the information from the survey, the value of a statistical farm animal life would be about $700. That would be over and above the productive value of the animal net of inputs into animal production.

Multiplying a willingness to pay to save a sick pet of $1,608 by 4,500 sick animals per year yields the maximum possible benefit that the regulation could claim for saving sick animals at $7,236,000 per year.

3. Reduced risk of humans consuming food derived from animals that consumed contaminated food

In the RIA, the FDA states, "Humans may be exposed to pesticide residues or aflatoxins when they eat food from animals fed contaminated feed."[33] In reality, the regulation is unlikely to create any benefits of this type.

The FDA can claim no additional benefit for this proposed regulation from reduced exposure to violative pesticide residues, *in addition to all of the other regulations regarding pesticide use and contamination of food.* The US Department of Agriculture (USDA) 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 reported, the Pesticide Data Program tested 371 egg samples and 743 milk samples. Only two egg samples and no milk samples were found to be in violation of US pesticide regulations.[34] According the USDA, "the 2011 PDP report confirms that overall

30. GfK Custom Research North America, "AP-Petside.com Poll," April 2010, 5, http://surveys.ap.org/data%5CGfK%5CAP-GfK%20Petside%20Topline%20for%20final%20060710_4th%20release.pdf.
31. Jayson L. Lusk, F. Bailey Norwood, and Robert W. Prickett, "Consumer Preferences for Farm Animal Welfare: Results of a Nationwide Telephone Survey" (working paper, Department of Agricultural Economics, Oklahoma State University, Stillwater, OK, August 2007), 11, http://asp.okstate.edu/baileynorwood/Bailey/Research/InitialReporttoAFB.pdf.
32. FDA, "Analysis of Economic Impacts," 382.
33. RIA, 14.
34. USDA/Agricultural Marketing Service, Science, and Technology Programs, *Pesticide Data Program, Annual Summary*, Calendar Year 2011, February 2013, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5102692.

pesticide chemical residues found on the foods tested are at levels below the tolerances established by the Environmental Protection Agency (EPA) and do not pose a safety concern."[35] They continue:

> Similar to previous years, the 2011 report shows that overall pesticide chemical residues found on foods tested are at levels well below the tolerances set by the EPA. The report does show that residues exceeding the tolerance were detected in 0.27 percent of the samples tested. Some residues were found with no established tolerance levels or tolerance exemptions, but EPA has determined that the extremely low levels of those residues are not a food-safety risk, and the presence of such residues does not pose a safety concern.[36]

The EPA states, "The newest data from the PDP program confirm that pesticide residues in food do not pose a safety concern for Americans. EPA remains committed to a rigorous, science-based, and transparent regulatory program for pesticides that continues to protect people's health and the environment."[37]

The FDA can claim no benefit for this proposed regulation from reduced human exposure to aflatoxin. According to Feddern et al. citing Biswas et al., "Aflatoxin or ochratoxin residues in meat are uncommon and rarely found."[38] Moreover, 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 controls 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.

4. Reduced risk of recalls: an illusory "benefit"

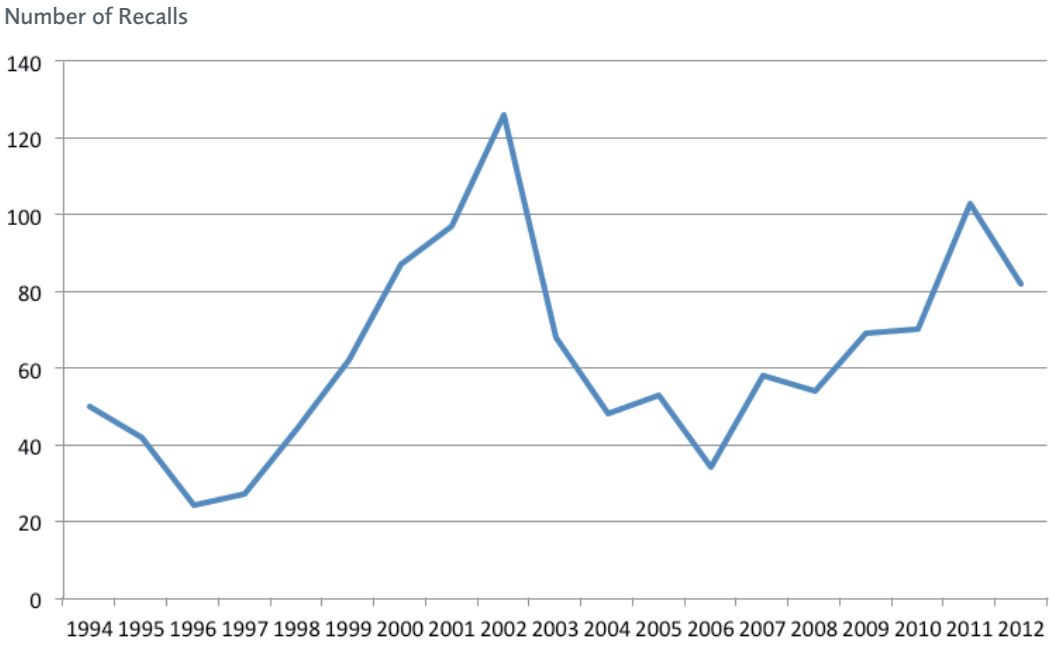
The FDA repeatedly claims in the RIA that another benefit of the regulation is reduced recalls of animal food. For example, "The proposed rule would require specific controls that would help prevent animal food recalls and facilitate the tracking of animal food where recalls are necessary."[39] And "by reducing the probability of contamination, the proposed rule would avoid some of these recalls, and thus some of the direct losses attributable to livestock feed recalls."[40] And "we have described how improved animal food safety systems can reduce the number of recalls."[41] And, "FDA would not expect the level of activity required for an actual recall to change, and would expect the annual number of recalls to decrease."[42]

The FDA offers no evidence to support its assertion that a benefit of the regulation will be reduced recalls. It is an oft-repeated assertion by government officials and quality-control–system salesmen. But the evidence proves the opposite. More regulation leads to more recalls, not fewer.

The Food Safety Inspection Service Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Final 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.[43]

---

35. USDA/Agricultural Marketing Service, Science and Technology Programs, "Program Announcement: USDA Releases 2011 Annual Summary for Pesticide Data Program," news release, February 22, 2013, AMS No. 014-13, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5049944
36. Ibid.
37. Ibid.
38. Vivian Feddern et al., "Aflatoxins Importance on Animal Nutrition," in *Aflatoxins: Recent Advances and Future Prospects*, ed. Mehdi Razzaghi-Abyaneh (Rijeka, Croatia: InTech, 2013); and A. K. Biswas et al., "Food Safety Concerns of Pesticides, Veterinary Drug Residues and Mycotoxins in Meat and Meat Products," *Asian Journal of Animal Sciences* 4 (2010): 46–55.
39. RIA, 17.
40. Id., 21.
41. Id., 23.
42. Id., 71.
43. 61 Fed. Reg. 144, 38,806.



Source: USDA, Food Safety and Inspection Service, "Recall Case Archive," last modified February 5, 2014, http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive.

That regulation is a preventive-control type of regulation, similar in many ways to the FDA's proposed regulations for human and animal food. The graph below shows the number of meat and poultry recalls reported by the Food Safety Inspection Service on its website.

Between 1994 and 1997, the average annual number of recalls was less than 36. Since 1998 the average annual number of recalls has exceeded 70.[44] 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 of the regulation.[45] If reduced recalls would be a benefit of regulation, then increased recalls would be a cost of regulation. Based on the evidence, the FDA should expect that this 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.

Recalls are not a completely bad thing. It is certainly better to recall defective products than to have them consumed. It is quite possible that it is more efficient to have a very low rate of product defects at a given product price and to deal with those defects with recalls, than to have a somewhat lower rate of product defect at a higher product price with fewer recalls. If the FDA believes that fewer recalls are unambiguously better than more recalls, then it needs to explain exactly (1) how its regulation for animal food differs from the FSIS regulation for human food in a way that its regulation will lead to fewer recalls for animal food while the FSIS regulation has led to more recalls for human food; and (2) 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 the contamination of animal food with contaminants or human pathogens is reduced to a degree that humans or animals are harmed less frequently than they would be without the regulation.

---

44. USDA, Food Safety and Inspection Service, "Recall Case Archive," last modified February 5, 2014, http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive.
45. Ibid.

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.[46]

Similar assertions without evidence occur repeatedly.[47] The apparent assumption is that the regulations will reduce adulteration because they are intended to reduce adulteration. The FDA appears to have no scientific evidence that the regulation will make animal food safer. The FDA offers no evidence on the effectiveness of the proposed regulatory controls at reducing contamination. The FDA only states that there are observed and potential problems with animal food and then describes the proposed regulation. 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 NPRM notes that in the past, the FDA developed current good manufacturing practices for human food and required seafood and juice processors to implement hazard analysis and critical control points (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.[48] The US Department of Agriculture has mandated HACCP for meat and poultry processors.[49] Retrospective analysis of these regulatory initiatives could determine whether the regulations reduced contamination or recalls 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. The NPRM asserts that "these efforts have contributed to progress on food safety,"[50] but neither the NPRM nor the RIA cites any retrospective studies that demonstrate this.

In fact, the FDA cites early in the document that its use of Hazard Analysis Critical Control Points (HACCP) as justification for this rule, which is essentially a rule mandating HACCP. These are poor examples to use. The first FDA HACCP rule was the seafood rule. The FDA has never evaluated the effectiveness of this rule.[51] For example, in its RIA, the FDA estimated that about half of the benefits of this rule would be from reducing *vibrio Vulnificus* from 60 cases per year to between 30 and 48 cases per year.[52] In 2011, the CDC reported that there were 113 cases.[53]

The FDA also cites its Juice HACCP rule.[54] In fact, virtually the entire problem addressed by the rule was caused by the fact that apples were pressed into juice and sold as raw. The problem was solved by pasteurization, not the complicated recordkeeping associated with HACCP. Neither of these rules demonstrates the success of government-mandated HACCP.

---

46. RIA, 13.
47. For specific examples, see RIA, 9, 13, 15, 16, 17, 21, 23, and 24.
48. NPRM, 64771.
49. Id., 64739–70.
50. Id., 64739.
51. "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," 60 Fed. Reg. 242 (December 18, 1995), 65096.
52. Id., 65186.
53. National Center for Emerging and Zoonotic Infectious Diseases, Division of Foodborne Waterborne, and Environmental Diseases, Centers for Disease Control, *National Enteric Disease Surveillance: COVIS Annual Summary, 2011* (August 2013), http://www.cdc.gov/ncezid/dfwed/PDFs/covis-annual-report-2011-508c.pdf.
54. FDA, "Juice HACCP," last modified August 21, 2013, http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006803.htm.

Current concerns about jerky treats for pets illustrate why it is invalid to simply assume that a regulation can entirely eliminate a risk. "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 3000 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."[55]

The FDA has investigated numerous 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 or what is being done to the jerky treats that is causing the problem for pets. 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 once this 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 the estimates of the monetary value of the human- and animal-health risks associated with animal food gives the *maximum possible* benefit that the regulation could claim of $30,250,000 per year. Since the FDA presents no evidence that the regulation will be effective, the benefits could be as low as zero dollars.

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.[56] The FDA has presented almost no data to support that estimate of effectiveness in the context of the human food rule and no evidence of effectiveness of the proposed animal food regulation. However, if we make the generous and convenient assumption that the proposed animal food regulation is equally effective as the FDA claimed the human-food proposed regulation would be (and there is no evidence that it will be), then the estimated annual benefits for it are about $16.9 million.

NET BENEFITS OF VIABLE REGULATORY ALTERNATIVES

Executive Order 12866 instructs agencies to design their regulations in the most cost-effective manner and to "propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."[57] 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 in on the final rule.[58] These costs are 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 this estimate understates the overall costs 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*, appear to have the food-safety problem very much in control. As we pointed

55. FDA, "Questions and Answers Regarding Jerky Pet Treats," last modified October 22, 2013, http://www.fda.gov/animalveterinary/safetyhealth/productsafetyinformation/ucm295445.htm.
56. FDA, "Analysis of Economic Impacts."
57. Exec. Order No. 12866, Sec. 1(b)(5) and Sec. 1(b)(6).
58. RIA, 9.

out earlier, there doesn't 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, these 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 this rule will produce safer food.

The RIA presents annualized costs, but annualized costs are 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 (7 percent or 3 percent used), the total discounted cost is $6.7–15.7 billion.[59] No matter how you think about it, this is a substantial sum to be spending on unproven regulations. 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.

Table 2. Regulation benefit-cost analysis

COVERAGE OF REGULATION	BENEFITS	COSTS ANNUALIZED AT 7%	NET BENEFITS
Proposed regulation			
very small business, <$500,000 sales	$16.9 million	$128.75 million (6,603 facilities covered)	–$111.85 million
very small business, <$1,000,000 sales	$16.7 million	$119.90 million (6,124 facilities covered)	–$103.20 million
very small business, <$2,500,000 sales	$13.4 million	$86.92 million (4,325 facilities covered)	–$73.52 million
Proposed regulation plus foreshadowed provisions			
very small business, <$500,000 sales	$16.9 million	$145.79 million (6,603 facilities covered)	–$128.89 million
very small business, <$1,000,000 sales	$16.7 million	$136.77 million (6,124 facilities covered)	–$120.07 million
very small business, <$2,500,000 sales	$13.4 million	$98.42 million (4,325 facilities covered)	–$85.02 million
Pet food only regulation			
very small business, <$500,000 sales	$14.9 million	$8.56 million (439 facilities covered)	$6.34 million
very small business, <$1,000,000 sales	$14.7 million	$7.62 million (389 facilities covered)	$7.08 million
very small business, <$2,500,000 sales	$11.8 million	$5.90 million (300 facilities covered)	$5.9 million
Pet food only regulation plus foreshadowed provisions			
very small business, <$500,000 sales	$14.9 million	$9.69 million (439 facilities covered)	$5.21 million
very small business, <$1,000,000 sales	$14.7 million	$8.69 million (389 facilities covered)	$6.01 million
very small business, <$2,500,000 sales	$11.8 million	$6.70 million (300 facilities covered)	$5.10 million

Source: Authors' calculations using methods explained in text.

59. Authors' calculation based on one-time and annual cost estimates provided in the RIA.

Net benefits of alternatives

The FDA has a proposed regulation with different options for applying the regulation to very small businesses. This changes not only the estimate of costs but also the estimate of benefits for each alternative. To calculate 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." Our results show that 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. The FDA only provided cost information for that option at the strictest definition of very small business, so we are not able to provide accurate calculations for the more expansive definitions of very small business. We adjust the $17.04 million cost of the additional provisions for the strictest definition of very small business proportionally to the costs of the proposed provisions. Adding these costs 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. A pet food-only rule would apply to about six to seven percent as many facilities, but it would still achieve almost all of the benefits of the regulation covering all animal food facilities. Since no data indicate that non-pet animal food has been related to human salmonellosis, a pet food-only rule would lose none 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 nonpets, 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 costs. The figures in the table suggest that 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.

The FDA should refrain from issuing a final regulation until it has conducted a Regulatory Impact Analysis (including a risk assessment) that does the following:

- Uses 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.
- Assesses 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.
- Assesses whether emphasizing tracebacks and attribution might not create sufficient incentive for manufacturers to exercise due diligence.

- Assesses 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.
- Assesses whether a regulation targeted at pet food only could achieve most of the goals of the proposed regulation at lower cost.
- Demonstrates 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.

Given the language of the Food Safety Modernization Act, the FDA may ultimately feel obligated to adopt a regulation similar to the current proposal, even if there is no market failure, the costs would exceed the benefits, or there is little evidence that the regulation would produce benefits. Nevertheless, the additional analysis recommended above would help ensure that the president, Congress, and the public are adequately informed about the consequences of this policy choice.