

April 9, 2014

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Food for Animals [RIN 0910-AG10]

Dear Commissioner Hamburg:

I am writing you for two reasons. First, I want to commend certain Food and Drug Administration (FDA) employees for the important contributions made by them during small business roundtables hosted by impacted industries designed to disseminate information and to answer questions on the Food Safety Modernization Act rules. Secondly, I want to inform you of some small business concerns with the above-captioned rule. It is my hope that the FDA will consider the affected industries' comments and take them into consideration as the agency finalizes the proposed rule.

Background

The Office of Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA), so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),¹ as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),² gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives. The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.³ The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by

¹ 5 U.S.C §601 et seq.

² Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et. seq.).

³ Small Business Jobs Act of 2010 (Pub. L. 111-240) § 1601.

Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.⁴

As you know, the Food Safety Modernization Act (FSMA)⁵ increases the FDA's oversight and enforcement authority over the nation's human and animal food supply. FSMA will likely cause a sea-change in this nation's business practices affecting how human and animal food is grown and imported into this country, and on the food safety responsibilities of food suppliers, food wholesalers and food importers, many of whom are small businesses.

Advocacy was approached by numerous small food import, food supplier and food wholesaler businesses, and their representatives, concerned about how regulations promulgated under FSMA might impact their business practices and revenues. Those entities asked Advocacy to closely follow and participate in the promulgation of the FSMA rules. We have summarized our outreach and some of the small business concerns below in section I, and we provide you with our thoughts on the Current Good Manufacturing Practice (CGMP) for Animal Food proposed rule below.

I. Advocacy has reached out to small business and to the FDA to determine the impact of the FSMA regulations issued by the agency.

In an effort to be responsive to those small business concerns and to be better educated on FSMA issues, Advocacy participated in three roundtables organized by affected food stakeholders, including the Coalition of Small Food Businesses, the National Association for the Specialty Food Trade, the Port of Los Angeles, Innovate Hawaii and the Hawaii Foreign Trade Zone 9. These organizations invited Advocacy to participate in the roundtables to hear how small businesses might be impacted by the FSMA rules and to discuss alternatives that might reduce those impacts. The roundtables took place in Washington D.C. on January 17, 2013 and December 5, 2013 and in Los Angeles, California on September 24, 2013. The roundtables principally involved FSMA rules on prior notice for imported foods, foreign supplier verification and third-party accreditation. Advocacy invited the FDA to participate in the roundtables, and I am thankful that your agency did so as their input allowed the stakeholders to directly interact with FDA officials. I want to thank the following FDA employees whose participation in the roundtables was invaluable: Leslie Kux, Rebecca Buckner, Charlotte Christin, Brian Pendelton, Sharon Mayl, and Captain Larry Howell. Following the roundtables, my office shared what we learned from the affected industries with FDA personnel during the respective rules' comment periods.

II. Advocacy is concerned that the CGMP for Animal Food proposed rule's analysis requires more clarification and that the application of the analysis may be too broad resulting in greater economic impacts on small businesses.

⁴ *Id.*

⁵ Pub. L. 111-353.

On October 29, 2013, the FDA published the Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventative Controls for Food for Animals proposed rule in the *Federal Register*.⁶ The regulation applies to pet food and livestock feed. The rule would regulate the manufacturing, processing, packing, or holding of animal food in two ways. It would implement new current good manufacturing practice (CGMP) regulations, and it would include new preventative control provisions on animal food facilities that are required to register with the FDA under the FDA's current food facility registration regulations.

Under section 603 of the RFA whenever an agency is required to publish a notice of proposed rulemaking for any proposed rule, the agency must prepare and make available for public comment an initial regulatory flexibility analysis (IRFA).⁷

I commend the FDA for complying with this important RFA provision. My staff reviewed the rule's IRFA along with the Preliminary Regulatory Impact Analysis (PRIA) prepared by the FDA.⁸ Advocacy is concerned about the sufficiency of FDA's assumptions and conclusions relative to the rule's costs and benefits. In this rule the FDA relies on an April 2011 Eastern Research Group report that estimates the impacts of a working version of a process controls rule the agency had been developing prior to the passage of FSMA for its analysis of costs.⁹ The FDA also utilizes a cost methodology developed for a proposed rule to revise human food CGMPs under section 418 of the Food, Drug and Cosmetic Act.¹⁰ This seems atypical as FDA usually uses a qualitative risk analysis to serve as the basis for its analysis for costs. Advocacy is also concerned about the FDA's admission that due to a lack of data it cannot quantify the benefits of the regulation.¹¹

As I talk with small businesses throughout this country about regulatory burdens, it is apparent that they want rules that they understand and a process that will allow them to file informed and responsive comments. They also want predictability and certainty about their responsibilities and enforcement exposure under the proposed rules. It is my hope that by presenting you with our thoughts on some of the underlying methodologies and assumptions used by the FDA in the CGMP for animal food proposed rule, and some thoughts on possible alternative approaches, the end result will be an improved and more transparent final rule for small businesses.

A. The data used in the rule's PRIA and IRFA require clarification and consistency of application, especially as to the rule's assumptions regarding costs and firm size categorization.

⁶ 78 Fed. Reg. 64736 (October 29, 2013).

⁷ 5 U.S.C §603.

⁸ Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis and Unfunded Mandates Reform Act Analysis available at <http://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm366905.pdf>.

⁹ See PRIA at pages 7 and 8.

¹⁰ See PRIA at page 8.

¹¹ See PRIA at page 9.

1. Advocacy was unable to determine the reason for the discrepancy in annualized cost estimates as presented in the proposed rule versus the PRIA.¹² At a 7 percent discount rate over 10 years (year dollars not provided), the proposed rule lists the annualized costs to Very Small Businesses (VSB) as \$95 million, \$89 million, and \$65 million respectively for the \$500,000, \$1 million, \$2.5 million annual revenue categories. By contrast, for the same time period and discount rate, the PRIA lists annualized costs as \$128.75 million, \$119.90 million, and \$86.92 million for the same respective annual revenue categories. Advocacy's Table 1 summarizes the one-time and annualized costs as presented in the proposed rule and PRIA according to VSB size categories.¹³
2. Advocacy commends the FDA for complying with the FSMA requirement that it take small businesses into consideration while promulgating rules. In the rule the FDA has offered compliance flexibility to small businesses and VSB. The proposed rule in Section 507.3 defines small businesses as those businesses "employing fewer than 500 persons" and provides these small businesses with a compliance date 2 years from the publication of the final rule.¹⁴ However, both the overall cost impacts of the rule as well as the cost impacts to small businesses in the "fewer than 500 persons" category are somewhat unclear and difficult to distinguish from the more detailed analysis of cost impacts to VSB. The PRIA appears to require the reader to aggregate compliance category specific cost totals across multiple tables. In the final rule and its RIA, it would be helpful if FDA more clearly distinguished these cost impacts with a summary table that precedes the detailed analysis, or offered further detail as to why FDA is unable to provide these estimates.
3. While the PRIA provides adequate detail on impacts to VSB by compliance cost categories, the IRFA section (contained within the PRIA) could benefit from some additional clarification and consistency in presentation.¹⁵ The PRIA provides robust detail on cost impacts for various compliance activities, such as monitoring and sanitary controls. In addition, these detailed cost estimates generally present impacts according to the consistent firm size categories of: less than 20 employees, 20-99 employees, 100-499 employees, and more than 500 employees. By contrast, the IRFA does not present consistent firm size categories and does not provide consistent shipment value and cost information for the analyzed industry sectors.¹⁶ If the uneven presentation of information in the IRFA is due to data limitations, it would be helpful if FDA provided this clarification in the final rule's Final Regulatory Flexibility Analysis (FRFA).

¹² 78 Fed. Reg. 64818.

¹³ See, Appendix A, Table 1.

¹⁴ See the PRIA at page 7.

¹⁵ See the PRIA at page 97.

¹⁶ See, Appendix A, Table 2. *Determination of Significant Impact on Substantial Number of Small Entities, as Presented in IRFA.*

4. Advocacy suggests that the FRFA should offer greater specificity regarding the firm size category under discussion. In several places in the IRFA, the FDA refers to “small” or “smallest” or “largest” firms in discussing cost to shipment value ratios, but it is difficult to link these terms to specific size categories.¹⁷ For example, the IRFA states, “The average annualized cost of about \$17,900 per facility represents 2.72% of the average value of shipments for the small dog and cat manufacturing facilities, 1.270% of the average value of shipments for all facilities with fewer than 20 employees, and 0.07% or less for the larger facilities.”¹⁸ Using our analysis, it was possible to determine that “small” in this statement refers to facilities with fewer than 10 employees since the IRFA listed an average annual shipment value of \$660,000 for this size category. However, it is not clear to Advocacy how to solve for the specific size category of “larger” facilities since the IRFA does not present a corresponding shipment value. Given that this rule specifically defines “small business” as a business with fewer than 500 employees, greater specificity in referencing subcategories of firm size would prove particularly helpful for small businesses.

B. Advocacy has heard from small food producers, breweries and farmers who are concerned that the proposed regulation is too broad in its application and that the FDA has not adequately analyzed the economic impact of the rule on their industries.

1. Diverted food production materials from human food manufacturers that are placed into the animal food supply chain when the materials are not usable for human food.

Grocery manufacturing representatives told Advocacy that the proposed rule would impact manufacturers of food intended for human consumption that are placed into the animal food supply chain when the materials are not usable for human food. These products are referred to by industry as “diverted food production materials.” Examples of diverted food products include items such as citrus peels, corn husks, peanut shells, and used fryer oil. Industry representatives suggest that the FDA failed to adequately provide for a regulatory framework for such products; failed to analyze the impacts of including these types of products in the requirements of the rule; and failed to consider reasonable alternatives to the inclusion of diverted food production materials in the rule. The small business representatives that approached Advocacy recommend that the FDA should revise the proposed regulation so that it applies only to materials that are manufactured with the intent to market a finished product as animal food. They suggest that this “intended use” approach would be consistent with the definition with the statutory definition of “animal feed” as an “article which is intended for use for food for animals other than man.” Industry representatives asked Advocacy to bring these matters to the FDA’s attention and encourage the agency to re-publish the animal

¹⁷ *Id.*

¹⁸ See the PRIA at page 99.

feed rule seeking public comment with an eye towards diverted food production materials.

Upon review of the RIA and IRFA contained in the proposed rule, Advocacy did note that the analysis does not specifically discuss or analyze food product such as diverted food production materials. However, in the rule the FDA alludes to the possibility that the regulation would require CGMP and preventative control (including hazard analysis) of these products.¹⁹ In light of this uncertainty, Advocacy believes the FDA should provide industry with more transparency about whether the regulation covers these items, and if so, the agency should analyze the economic impacts of their inclusion in the Final Regulatory Impact Analysis and in the FRFA.

2. Brewery transfer of spent grains to farms for livestock feed.

Advocacy was approached by small brewers who are members of the Brewers Association. The association represents more than 2,700 small and independent brewery businesses. Owners of small breweries and farmers told Advocacy that historically brewers sell, or give, spent grains to farmers for use as livestock feed as it serves as a cheap source of protein for the animals. The small brewers are concerned that the proposed rule will have a significant economic impact on their businesses as it will either require them to comply with certain risk assessment, testing and recordkeeping requirements, or to pay to dispose of grain, perhaps in landfills. They believe that forcing the industry to incur these costs is unwarranted as there is no evidence that the practice of providing spent grain to farmers is anything other than safe.

The proposed rule does indicate that the FDA intends for the rule to cover breweries and distilleries that sell spent grains intended as food for animals. The FDA notes that, "Because those spent grains are not alcoholic beverages themselves, and they are not in a prepackaged form that prevents any direct human contact with the food, the Agency tentatively concludes that subpart C of this proposed rule would apply to them."²⁰ Affected small business owners and representatives are asking that the FDA to conduct a risk assessment of the use of spent brewers' grain by farmers prior to imposing expensive new regulations and controls on the industry.

This is the type of industry-specific impact that the RFA requires the promulgating agency to analyze in the rule's IRFA. The FDA did not include any discussion in the RFA section of the rule relative to the economic impact of this provision on small breweries (who must now either comply with the CGMP and hazard analysis provisions of the rule or incur the cost of disposing of the spent grains). The rule does not analyze the impacts on small farms that rely on the spent grains as a low-cost supplemental source for animal protein and hydration.

¹⁹ 78 Fed. Reg. 64765.

²⁰ *Id.*

Advocacy would encourage the FDA to revisit this issue as the agency's use of the term "tentatively" in this section of the proposed regulation signals a willingness to consider an alternative approach.²¹ At the very least the FDA should have sought public comment on the appropriateness and impact of having to comply with the provisions under subpart C of the rule.

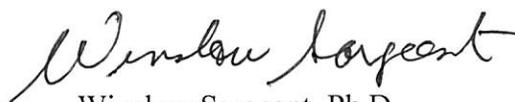
Conclusion

Advocacy requests that the FDA consider and take the affected industries' comments into consideration as the agency finalizes this proposed rule. Also, in light of the economic impact data provided by the affected industries, Advocacy encourages the FDA to revisit some of its cost assumptions in the final rule.

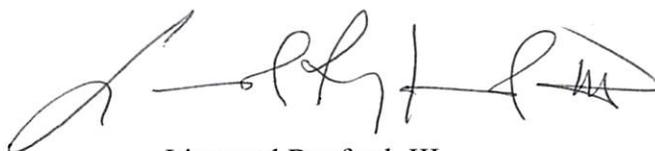
The RFA requires that final rule must contain a Final Regulatory Flexibility Analysis (FRFA).²² Section 604(a)(2) provides that the FRFA must summarize significant issues raised by the public comments in response to the IRFA and an assessment by the agency of those issues. Section 604(a)(5) requires that the agency must include a statement containing the factual, policy and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives were rejected. Advocacy encourages the FDA to entertain and analyze the aforementioned alternatives recommended by the affected stakeholders, and to discuss its reasons for accepting or rejecting those recommendations in the final rule.

If you have any questions or concerns, please do not hesitate to contact me or Linwood Rayford at (202) 205-6533, or linwood.rayford@sba.gov.

Sincerely yours,



Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy



Linwood Rayford, III
Assistant Chief Counsel

Cc: Howard Shelanski, Administrator, Office of Information and Regulatory Affairs

²¹ *Id.*

²² 5 U.S.C. §604.

Appendix A. Summary of Small Entity Impacts

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Food for Animals; Proposed Rule (78 FR 64736)

(PRIA and IRFA as cited at 78 FR 64818, available at <http://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm366905.pdf>)

Table 1. Overall Small Entity Costs as Presented in Proposed Rule and PRIA (millions)

Impacted Small Entities	PRIA Estimated One-time Compliance Costs (PRIA Table 1, p. 9)	PRIA Estimated Annualized Costs (at 7% discount rate, over 10 yrs, PRIA Table 1, p. 9)	Preamble Estimated Annualized Costs (at 7% discount rate, over 10 yrs, 78 FR 64738)
<i>Small Businesses (Less than 500 employees)</i>	Not presented	Not presented	Not presented
<i>Very Small Businesses</i>			
< \$500,000 sales revenue	\$ 100.74	\$ 128.75	\$95
< \$1,000,000 sales revenue	\$ 95.47	\$ 119.90	\$89
< \$2,500,000 sales revenue	\$ 74.71	\$ 86.92	\$65

Table 2. Determination of Significant Impact on Substantial Number of Small Entities, as Presented in IRFA

IRFA Affected Small Entities by Industry Sector	Size Category (No. Employees)	IRFA Estimated AVE Annualized Costs Per Facility (at 7% discount rate, over 10 yrs)	IRFA Estimated AVE Value Annual Shipments	IRFA Estimated Percent Ratio: AVE Annual Costs/AVE Value Shipments	Significant Impact on Substantial Number of Small Entities (SINOSE) Determination
<i>"small entities"</i>	Not presented	\$14,700 to \$20,100	Not presented	Not presented	Not presented
<i>Breweries</i>	Not presented	Not presented	Not presented	Not presented	Not presented
<i>Dog and cat food companies (NAICS 311111)</i>					
<i>"small entity"</i>	500 or fewer	Not presented	Not presented	Not presented	
	Fewer than 10	\$ 17,900	\$ 660,000	2.72%	
	Fewer than 20	\$ 17,900	Not presented	1.27%	SINOSE
	100 to 499	\$ 17,900	> \$216,000,000	Not presented	
<i>"larger facilities"</i>	Not presented	\$ 17,900	Not presented	0.07%	
<i>Other Animal Food Manufacturing (NAICS 311119)</i>					
<i>"small entity"</i>	500 or fewer	Not presented	Not presented	Not presented	
	Fewer than 5	Not presented	\$ 1,180,000.00	1.46%	SINOSE
	100 to 499	Not presented	> \$86,000,000	Not presented	
<i>"larger facilities"</i>	Not presented	Not presented	Not presented	0.26%	
<i>Rendering facilities (NAICS 311613)</i>					
<i>"small entity"</i>	500 or fewer	Not presented	Not presented	Not presented	
	Fewer than 5	Not presented	\$ 1,600,000	1.02%	
	Fewer than 20	Not presented	Not presented	likely > 1%	SINOSE
	100 to 499	Not presented	\$ 46,620,000	Not presented	
<i>"larger facilities"</i>	Not presented	Not presented	Not presented	0.44%	
<i>Farm Product Raw Material Merchant Wholesalers (NAICS 4245)</i>					
<i>"small entity"</i>	100 or fewer				

IRFA Affected Small Entities by Industry Sector	Size Category (No. Employees)	IRFA Estimated AVE Annualized Costs Per Facility (at 7% discount rate, over 10 yrs)	IRFA Estimated AVE Value Annual Shipments	IRFA Estimated Percent Ratio: AVE Annual Costs/AVE Value Shipments	Significant Impact on Substantial Number of Small Entities (SINOSE) Determination
	2 employees	Not presented	\$ 4,060,000	Not presented	
	100 to 499	Not presented	\$ 560,470,000	Not presented	
"smallest of these facilities"	Not presented	Not presented	Not presented	0.41%	"UNLIKELY" SINOSE
"largest of these facilities"	Not presented	Not presented	Not presented	0.12%	"UNLIKELY" SINOSE
<i>Miscellaneous Nondurable Goods Merchant Wholesalers (NAICS 4249)</i>					
"small entity"	100 or fewer				
	1 employeey	Not presented	\$ 432,000	Not presented	
	5 or more	Not presented	Not presented	< .52%	
	100 to 499	Not presented	\$ 221,660,000	Not presented	
"smallest of these facilities"	Not presented	Not presented	Not presented	3.51%	SINOSE