

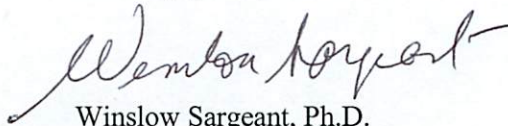
small entity exemption threshold clearly based on the quantified costs and benefits associated with small entities.

### **Conclusion**

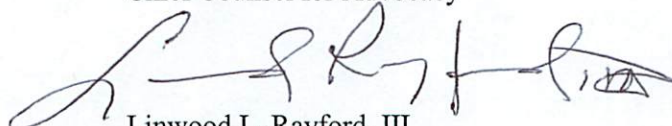
Advocacy encourages the FDA to revisit its analysis of the small business impacts of this regulation, and to be more transparent about its assumptions underlying the establishment of a compliance exemption based on covered entities' annual revenue in the final rule.

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](mailto:linwood.rayford@sba.gov).

Sincerely yours,



Winslow Sargeant, Ph.D.  
Chief Counsel for Advocacy



Linwood L. Rayford, III  
Assistant Chief Counsel Advocacy

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

revenues in an effort to estimate the rule's costs. Advocacy will defer to the affected industries' comments relative to the reasonableness of the rule's requirements and impacts on best business practices. Advocacy's comments will address FDA's assumptions contained in the IRFA about the affected entities' size composition and revenues.

First, Advocacy appreciates FDA's public commitment to continue to evaluate the impacts of this rule on small businesses.<sup>12</sup> Also, we acknowledge FDA's compliance with the RFA's requirement that it assess significant alternatives designed to reduce the economic burden of the rule on small businesses. The rule provides three (3) significant alternatives designed to minimize the impacts of the rule: 1) An exemption for any firm that has less than \$500,000 in annual revenues; 2) FDA allows affected businesses to seek a waiver if they can show that the waiver will not result in transportation of food deemed to be unsafe for human and animal health; and 3) the FDA will grant longer compliance periods for small businesses based on the business' annual revenue and it having less than 500 employees.

In the IRFA, the FDA defines the various covered entities as being "small" if they have less than \$500,000 in annual revenues.<sup>13</sup> Advocacy suggests that the FDA gives no explanation, nor provides any data, to justify its decision to set the exemption threshold at that amount. Traditionally, promulgating agencies utilize the SBA's size standards to determine threshold cut-offs for small business exemptions or exclusions. On its face, the FDA's size threshold is inconsistent with the SBA size standards and the current data on small entities. Looking at Advocacy's firm size data (see <http://www.sba.gov/advocacy/firm-size-data>), it is clear that many entities that would be considered small by the SBA size standards would not be considered small for the purposes of this rule because they have revenues exceeding the \$500,000 threshold. The estimated average revenue for many of these firms under 500 employees is over \$6,000,000. Consequently, it makes it difficult for many small entities to determine how they fit into the rule and the small entity cost calculations since they may or may not be small depending on different definitions and criteria.

Without any data on incremental costs and benefits, it will be difficult for small businesses to evaluate whether the \$500,000 threshold is correctly set, or if it needs to be raised or lowered. The lack of specifics also makes it difficult for interested small businesses to evaluate and comment on the proposed exemption threshold. FDA notes in the IRFA that it could increase the threshold for the small entity exemption or even exempt all small entities.<sup>14</sup> The FDA dismisses exempting all small entities because it assumes that the benefits from regulating these entities outweigh the cost savings to the entities. Yet, there is no evidence in the IRFA to support this assertion. The FDA should consider conducting further analyses to assess the impacts of various thresholds in terms of costs and benefits associated with small entities. Otherwise, it is not clear why the proposed exemption threshold is set at \$500, 000, which is below the SBA size standard level. The information in the IRFA implies that increasing the threshold may not increase the public health risks while yielding substantial burden reduction to small entities.

Given the lack of robust quantitative data in the PRIA, and to stimulate meaningful public comment on the rule's exemption threshold, FDA should re-establish a small entity size standard to be consistent with SBA size standards and recent small business data. This would result in a

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<sup>12</sup> PRIA, page 84.

<sup>13</sup> PRIA, page 80.

<sup>14</sup> *Id.*



“sanitary transportation rule”).<sup>7</sup> In the preamble of the rule, the FDA notes that the provisions of this regulation are meant to cover food shippers, receivers, or carriers (motor vehicle and rail) engaged in food transportation in the U.S. All told FDA estimates that the rule will impact 83,609 entities. However, the estimate does not specify how many of the entities are deemed to be small businesses.

Advocacy was approached by rail carrier representatives, including the American Short Line and Regional Railroad Association (ASLRRA) and the Association of American Railroads (AAR). They voiced concern about how the sanitary transportation rule would impact their business practices and revenues if finalized. The representatives were pleased that the rule is premised on utilizing best industry practices in an effort to reduce the overall economic impact. They voiced pride in the fact that current industry best practices have resulted in very few cases of foodborne illnesses directly attributable to rail carriers over the years. However, the representatives voiced concern about the rule’s potential to muddy current best practices, because the regulation’s requirements will apply uniformly across the entire United States food transportation sector. In the end, the rail representatives want specificity on the applicability of the rule’s revenue based exemption, and clarity on how the regulation will impact current industry best practices.

Section 603 of the RFA generally requires agencies to prepare an Initial Regulatory Flexibility Analysis (IRFA) to accompany every proposed rule. In summary, the agency must identify the number of small entities likely to be impacted by the rule, provide a description of projected reporting or recordkeeping requirements of the rule, and provide a description of any significant alternatives to the proposed rule which minimizes any significant economic impacts on small businesses.<sup>8</sup>

Pursuant to Advocacy’s mandate under the RFA, my office has reviewed the sanitary transport rule and the FDA’s Preliminary Regulatory Impact Analysis (PRIA)<sup>9</sup> which contained the IRFA. Advocacy is pleased that the FDA concluded that this regulation will have a significant impact on a substantial number of small entities,<sup>10</sup> and therefore the agency’s completion of the IRFA is appropriate. This letter is meant to encourage the FDA to improve the transparency of the rule’s RFA analysis. By improving the analysis, the FDA will give affected small entities more information on the underlying assumptions used in the regulation. This will hopefully lead to the specificity and clarity desired by the food transport sectors covered by the rule.

**Data limitations make it difficult to assess the reasonableness of FDA’s revenue based small business exemption.**

While the FDA is statutorily mandated by FSMA to undertake this regulation, the rule reflects a marked limitation in the data upon which the FDA relied while complying with Executive Orders 13563, 12866, and the analytical requirements of the RFA.<sup>11</sup> Because of the data limitations, FDA made various assumptions about some aspects of affected industries’ business practices and

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<sup>7</sup> 79 Fed. Reg. 7005 (February 5, 2014).

<sup>8</sup> 5 USC §603.

<sup>9</sup> Advocacy was unable to obtain a copy of the PRIA by utilizing the link contained in the proposed rule. We were able to obtain a copy of the PRIA by contacting the FDA directly. Industry representatives also reported that they were having difficulty obtaining the PRIA.

<sup>10</sup> PRIA, page 85.

<sup>11</sup> On pages 3 and 4 of the PRIA the FDA discusses an inherent difficulty in being fully able to assess the rule’s costs and benefits and the reasons how that inability reduces estimates on the effectiveness of the requirements of the rule to minimize potential adverse health effects in humans and animals.

July 31, 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: Sanitary Transportation of Human and Animal Food (RIN – 0910-AG98), 79 Fed. Reg. 7005 (February 5, 2014)**

Dear Commissioner Hamburg:

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),<sup>1</sup> as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),<sup>2</sup> 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.<sup>3</sup> 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 Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.<sup>4</sup>

**Small businesses are concerned about the impacts associated with this rule.**

As you know, the Food Safety Modernization Act (FSMA)<sup>5</sup> increases the United States Food and Drug Administration's (FDA) 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 and food transporters, many of whom are small businesses. My office has previously communicated with the FDA regarding our thoughts on how various FSMA regulations might impact the nation's small businesses.<sup>6</sup> I am writing today about the FDA's proposed rule on the sanitary transport of human and animal food (hereafter

<sup>1</sup> 5 U.S.C §601 et seq.

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

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

<sup>4</sup> *Id.*

<sup>5</sup> Pub. L. 111-353.

<sup>6</sup> See Advocacy's April 9, 2014, comment letter, Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Food for Animals, located at: [www.sba.gov/advocacy](http://www.sba.gov/advocacy).