

August 5, 2015

BY ELECTRONIC MAIL

Gina McCarthy, Administrator  
United States Environmental Protection Agency  
EPA East Bldg., Room 6428  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460

**RE: Comments on EPA's TSCA Reporting and Recordkeeping Requirements for Chemical Substances When Manufactured or Processed as Nanoscale Materials; Docket No. EPA-HQ-OPPT-2010-0572.**

Dear Administrator McCarthy:

The Office of Advocacy at the U.S. Small Business Administration (Advocacy) respectfully submits the following comments on the Environmental Protection Agency's (EPA) reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale. Small businesses are concerned that the rule will impose unnecessary and unjustified burdens on them and that alternatives exist that will reduce the economic impact of the rule on small entities while still accomplishing the agency's objective.

**The Office of Advocacy**

Congress established the Office of Advocacy under Pub. L. No. 94-305 to advocate the views of small entities before federal agencies and Congress. Because Advocacy is an independent body within the U.S. Small Business Administration (SBA), the views expressed by Advocacy do not necessarily reflect the position of the Administration or the SBA.<sup>1</sup> The Regulatory Flexibility Act (RFA),<sup>2</sup> as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA),<sup>3</sup> gives small entities a voice in the federal rulemaking process. For all rules that are expected to have a "significant economic impact on a substantial number of small entities,"<sup>4</sup> EPA is required by the RFA to conduct a SBREFA panel to assess the impact of the proposed rule on small entities,<sup>5</sup> and to consider less burdensome alternatives.

<sup>1</sup> 15 U.S.C. § 634a, *et. seq.*

<sup>2</sup> 5 U.S.C. § 601, *et. seq.*

<sup>3</sup> Pub. L. 104-121, Title II, 110 Sta. 857 (1996) (codified in various sections of 5 U.S.C. § 601, *et. seq.*).

<sup>4</sup> *See* 5 U.S.C. § 609(a), (b).

<sup>5</sup> Under the RFA, small entities are defined as (1) a "small business" under section 3 of the Small Business Act and under size standards issued by the SBA in 13 C.F.C. § 121.201, or (2) a "small organization" that is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field, or

The Small Business Jobs Act of 2010<sup>6</sup> requires agencies to give every appropriate consideration to comments provided by Advocacy. 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.

### **Agency Action**

On April 6, 2015, the U.S. Environmental Protection Agency (EPA) published a proposed rulemaking<sup>7</sup> to require reporting and recordkeeping for certain chemical substances when manufactured or processed at the nanoscale under Section 8(a) of the Toxic Substances Control Act (TSCA).<sup>8</sup> The proposal requires a one-time electronic reporting for both existing nanoscale materials and new discrete nanoscale materials. The rule would require both manufacturers and processors to report the same information to EPA, which includes the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information and existing data concerning environmental and health effects.

### **Advocacy Comments**

Small businesses and their representatives have expressed several concerns with EPA's proposed rulemaking to collect information on chemical substances as nanoscale materials.

- The sales threshold provided to qualify for the small business exemption included in the rule may be too low.
- The data underlying the regulation of processors under the rule may not be representative of such entities.
- The data sources used to determine the impacts on the nanomaterials industry overall are outdated.
- Nanomaterial firms engaged in research and development activities have requested additional guidance for the exemption provided to them in the proposal.

Advocacy urges EPA to consider small business' recommendations to address these important concerns.

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(3) a "small governmental jurisdiction" that is the government of a city, county, town, township, village, school district or special district with a population of less than 50,000 persons. 5 U.S.C. § 601.

<sup>6</sup> Pub. L. No. 111-240, § 124 Stat. 2504 (2010).

<sup>7</sup> Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements, 80 Fed. Reg. 18330 (proposed April 6, 2015) (to be codified 40 C.F.R. pt. 704.20).

<sup>8</sup> 15 U.S.C. § 2607(a) (1976).

## I. EPA Should Adjust the Small Business Exemption for Inflation

Under the proposed rule, EPA would only provide a small business exemption for companies with sales of less than \$4 million per year.<sup>9</sup> Small businesses and their representatives have expressed concerns that this low sales threshold is too low. The nanotech industry is comprised of new and developing startup firms that receive significant capital investments to actualize nanoproducts. The small businesses are concerned that establishing a reporting and recordkeeping requirement for companies with \$4 million or more in revenue would place an administrative burden on businesses focused on innovation. This will also create a chilling effect for new and developing start-ups below the \$4 million threshold, those that are positioned to grow rapidly.

EPA has the authority to adjust this sales volume threshold whenever the Producer Price Index (PPI) for Chemicals and Allied Products has changed by more than 20 percent since the promulgation of the existing standard in 1988.<sup>10</sup> Based on the use of the PPI for Chemicals and Allied Products, Advocacy has determined that the PPI increased by 138 percent between 1988, the year in which the existing standard was promulgated, and 2014, the most recent year for which annual index data are available.

<b>Chemical Manufacturing (PCU325) Producer Price Index Adjustments</b>				
<b>PPI adjustment based on annual data (1988-2014)</b>				
<i>Year</i>	<i>PPI Index</i>	<i>Price</i>		
1988	113.0	\$ 4,000,000.00	Index point change	156.2
2014	269.2	\$ 9,529,203.54	Percent change	138%
Source: BLS Producer Price Index Industry Data (Chemical Manufacturing -- PCU325)				
<a href="http://data.bls.gov/cgi-bin/surveymost?pc">http://data.bls.gov/cgi-bin/surveymost?pc</a>				

<sup>9</sup> 80 Fed. Reg. at 18339. Under existing regulations, small manufacturers can qualify as small by meeting either of two standards. The first is that the company's sales are less than \$40 million per year and the company does not manufacture more than 100,000 pounds of an individual substance at any individual site owned or controlled by the company. The second is that the company's sales are less than \$4 million per year. EPA has stated that the 100,000 pound threshold in the first standard did not contemplate typical production volumes for nanoscale materials and is therefore proposing to eliminate that option for small businesses in this rulemaking. See General Reporting and Recordkeeping Provisions for Section 8(a) Information Gathering Rules, 40 C.F.R. § 704.3 (1988).

<sup>10</sup> 40 C.F.R. § 704.3(3): Inflation index. EPA shall make use of the Producer Price Index for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics, for purposes of determining the need to adjust the total annual sales values and for determining new sales values when adjustments are made. EPA may adjust the total annual sales values whenever the Agency deems it necessary to do so, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later...

*Recommendation:*

EPA should increase the existing annual sales value for the small business exemption from \$4 million to \$9.5 million to reflect the change in inflation over that period. Adjusting the sales value to reflect the true current economic sales value will exempt the number of small businesses contemplated by both TSCA and EPA's current regulations.

**II. EPA Should Address the Unique Role of Processors Separate from Manufacturers in its Proposed Rulemaking and Provide Data to Identify its Impacts on the Processors.**

**1. EPA should distinguish between the requirements for manufacturers and requirements for processors.**

EPA has proposed the same reporting and recordkeeping requirements for both manufacturers and processors even though the agency has defined manufacturers and processors as different types of entities.<sup>11</sup> Small businesses have expressed concerns that EPA does not address this distinction in the proposed rule, which creates uncertainty and could lead to wasteful duplication. It is not clear which activities are considered manufacturing and which are considered processing. In particular, based on EPA's description of "discrete forms" under the proposal, it is unclear when a processor's obligation to report such a substance is triggered.<sup>12</sup> Such ambiguity is not acceptable especially when noncompliance with a rule could trigger substantial penalties.

*Recommendation:*

The agency should provide a clearer distinction between manufacturers and processors with regard to this rulemaking by separately identifying the activities that would qualify an entity for each category, the substances required to be reported by each and any other relevant circumstances.

**2. EPA lacks quantitative data to support its certification under the RFA for the regulation of processors in the proposed rulemaking.**

EPA has certified under the RFA that the rule would not have a significant economic impact on a substantial number of small entities.<sup>13</sup> The RFA requires that the EPA publish a statement providing a factual basis for such a certification.<sup>14</sup> Advocacy interprets the "factual basis" requirement to mean that, at a minimum, a certification should contain a description of the number of affected entities and the size of the

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<sup>11</sup> Under EPA's definition a manufacturer means a person who imports, produces, or manufactures a chemical substance for commercial purposes, which includes activities such as importing, producing, or manufacturing with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer. A processor, on the other hand, is any person who processes a chemical substance or mixture for commercial purposes which includes the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. 40 C.F.R. § 704.3.

<sup>12</sup> See 80 Fed. Reg. at 18334.

<sup>13</sup> 80 Fed. Reg. at 18338-18339.

<sup>14</sup> 5 U.S.C. § 605.

economic impacts and why either the number of entities or the size of the impacts justifies the certification.

EPA's Economic Analysis (EA)<sup>15</sup> primarily relied on two reports for data and methodological approaches to analyze regulatory impact and assess the nanoscale industry: Lux Research, *The Nanotech Report* (Lux Report)<sup>16</sup> and BCC Research, *Nanotechnology: A Realistic Assessment* (BCC Report).<sup>17</sup> It is unclear whether either of the reports provide specific information on the number of processors that would be subject to the rule.

In determining the number of nanoscale firms that would be impacted by the rule, EPA derived samples from both the Lux Report and the BCC Report using the same sampling methodologies. Regarding the Lux Report, EPA states its sample is "representative of the U.S. nanomaterial manufacturers" but does not list processors.<sup>18</sup> For the sample derived from the BCC Report, EPA does not clarify the extent to which the number represents manufacturers or processors. EPA also appears to rely primarily on manufacturer data to determine the number of small businesses and the number of large businesses that would be impacted by the rule.<sup>19</sup> Based on EPA's description of the reports used, while it is clear that there is information on firms manufacturing nanoscale materials, there is no independent data on the number of processors that would be impacted by the rule.

*Recommendation:*

EPA should identify data on processors and assess such data to determine the number of small entity processors that would be impacted by the rule and its economic impact, under the RFA.

3. The uniform reporting standard fails to recognize the different, potentially higher administrative costs for processors.

Small business representatives have stated that the impacts on processors as a result of this rule will be different from those on manufacturers. For instance, the compliance and familiarization costs will likely vary for processors. In this rulemaking, EPA is proposing to use a single form to require reporting from both manufacturers and processors.<sup>20</sup> The form is largely based on the agency's PreManufacturer Notice (PMN)

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<sup>15</sup> Economic Analysis for the TSCA Section 8(a) Proposed Reporting Requirements for Certain Chemical Substances as Nanoscale Materials, U.S. Environmental Protection Agency, Office of Pollution, Prevention and Toxics, Economics, Exposure and Technology Division, Washington, D.C., [hereinafter Economic Analysis], available at: <http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OPPT-2010-0572-0002>.

<sup>16</sup> Lux Research: *The Nanotech Report*<sup>TM</sup>, 5<sup>th</sup> ed. (2007), [hereinafter Lux Report].

<sup>17</sup> BCC Research: *Nanotechnology: A Realistic Assessment* (2008), [hereinafter BCC Report].

<sup>18</sup> See Economic Analysis, *supra* note 21, at 2-2.

<sup>19</sup> *Id.* at 2-4 - 2-5.

<sup>20</sup> See Proposed Data Submission Form for TSCA 8(a) Reporting for Chemical Substances Manufactured and Processed as Nanoscale Materials, available at: <http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OPPT-2010-0572-0042>.

submission form.<sup>21</sup> PMN is a notification requirement for manufacturers (and importers) only.<sup>22</sup> According to small business representatives, processors are largely unfamiliar with the PMN process and as a result likely have limited experience in submitting information required to complete such a form.

Small businesses have expressed concerns that some processors may not have the regulatory sophistication or personnel to comply with the reporting requirements. As a result, these small businesses will incur the cost of third party training and other professional assistance. Such additional costs are not been included in the agency's EA. In addition, the agency has not considered other important cost factors in the EA such as the time and effort required to acquire, review and analyze the relevant information to determine whether a material meets the reportable criteria and whether or not a reporting obligation exists. In many cases, processors may not have the information and have to take additional steps to obtain the information from their suppliers or manufacturers. This may prove to be particularly burdensome for small processors with limited resources.

*Recommendation:*

EPA should thoroughly examine and consider the role of processors in the nanoscale industry as it relates to this rulemaking to provide a regulatory framework that is suitable to their unique position.

### **III. EPA Should Account for the Growth in the Nanomaterial Industry and Adjust its Baseline for Industry Size Calculations.**

1. EPA should apply the annual growth rate calculation methodology (utilizing the correct number of years) used in its sensitivity analysis to its primary economic analysis.

EPA currently assumes that the number of firms in the nanomaterials industry will remain constant or experience zero growth over the ten-year period of analysis.<sup>23</sup> While EPA justifies this assumption of zero percent growth based on "uncertainty in predicting the future nanomaterials market,"<sup>24</sup> this assumption is not consistent with the data points cited elsewhere in EPA's own EA.<sup>25</sup> Although EPA illustratively considers an alternate growth rate scenario in its sensitivity analysis,<sup>26</sup> EPA does not apply these growth rate calculations to its broader EA.

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<sup>21</sup> See PreManufacturer Notice for New Chemical Substances, available at: <http://www.epa.gov/oppt/newchemicals/pubs/pmnviewonly.pdf>.

<sup>22</sup> See PreManufacturer Notification, 40 C.F.R. § 720 (1983).

<sup>23</sup> See Economic Analysis, *supra* note 21, at 2-4.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at p. 6-1.

<sup>26</sup> *Id.* EPA uses the following annual growth rate formula in its sensitivity analysis:

$$\text{Annual growth rate} = \frac{\frac{\Delta \text{Number of firms}}{\text{Firms year 1}}}{(\text{Number of years})}$$

In its illustrative sensitivity analysis, EPA calculates an annual growth rate of 5.8 percent using the years 2011 and 2005 (a six year period).<sup>27</sup> However, given that the firm counts used in the calculation reflect 2008 and 2005 numbers (derived from the 2008 BCC Report and the 2005 NMSP ICR,<sup>28</sup> respectively), it is unclear why EPA uses the year 2011 to calculate the growth rate. When using what Advocacy believes is the correct year for the data, 2008, the denominator decreases from six to three years, producing an 11.6 percent annual growth rate.<sup>29</sup>

*Recommendation:*

EPA should apply its annual growth rate methodology to its estimate of the regulated community (described in section 2.2.4 of the EA) and recalculate subsequent analyses based on this consideration to more accurately reflect industry growth over time. Assuming EPA adopts the recommendation to apply the annual industry growth rate methodology used in its sensitivity analysis to its broader EA, EPA should amend its calculations to reflect the correct denominator (number of years). This recalculation would increase the total number of firms impacted by this rulemaking, including, potentially, the number of small firms affected.

2. EPA should adjust its baseline to reflect 2015 numbers.

Citing data from the BCC Report from 2008, EPA estimates that there are currently 823 nanomaterial firms in the United States.<sup>30</sup> Small business representatives are concerned with the use of severely outdated data sources to establish the size of the nanoscale industry. While this may have been a reasonable estimate when the BCC report was released seven years ago, it seems unlikely, given various indications of industry growth, that this number is an accurate representation of the industry at the time of this rulemaking in 2015.

*Recommendation:*

EPA should increase its outdated estimate of the number of nanomaterial firms to account for the annual industry growth between 2008 and 2015 and reflect the correct analytical baseline, which should be set at year 2015.

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<sup>27</sup>See Economic Analysis, *supra* note 21, at 6-1

<sup>28</sup> *Id.* See U.S. Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics. 2007. *Supporting Statement for EPA ICR No. 1198.05: Information Collection in Support of EPA's Stewardship Program for Nanoscale Materials.*

<sup>29</sup> 
$$\text{Annual growth rate} = \frac{\frac{\Delta \text{Number of firms}}{\text{Firms year 1}}}{(\text{Number of years})} = \frac{\frac{(823 - 611)}{611}}{(2008 - 2005)} = 0.116$$

<sup>30</sup> See Economic Analysis, *supra* note 21, at p. 2-4.

#### **IV. EPA Should Provide Additional Clarification for the Research and Development Exemption**

TSCA section 8(a) also provides an exemption for the manufacture or process of a chemical substance in small quantities for research and development (R&D).<sup>31</sup> EPA provides for this exemption in its proposed rulemaking.<sup>32</sup> In its preamble, the agency lists examples of R&D activities which includes the production (and sale) of a substance for use by others in their R&D activities.<sup>33</sup> Small businesses producing nanoscale substances for R&D purposes have expressed their uncertainty regarding their responsibility to ensure that the downstream user of their product limits the use of the substance to R&D activities only.

*Recommendation:*

The agency should clarify the obligation of both manufacturers and processors of R&D substances who sell to others and provide a clear description of the scope of their expected duties.

#### **Conclusion**

Advocacy urges EPA to follow small business' recommendations, provided above, to address the small business concerns with EPA's proposed rulemaking to collect information on chemical substances as nanoscale materials. Advocacy looks forward to continuing to work with EPA on this important matter. If you have any questions or need any further assistance, please contact me or Assistant Chief Counsel Tayyaba Waqar, at (202) 205-6790 or [twaqar@sba.gov](mailto:twaqar@sba.gov).

Sincerely,



Claudia Rayford Rodgers  
Acting Chief Counsel



Tayyaba Waqar  
Assistant Chief Counsel  
Office of Advocacy

Copy to: The Honorable Howard Shelanski, Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget

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<sup>31</sup> 40 C.F.R. § 704.5 (e).

<sup>32</sup> 80 Fed. Reg. at 18335.

<sup>33</sup> *Id.*