



April 17, 2017

VIA REGULATIONS.GOV

The Honorable Scott Pruitt
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain uses Under TSCA Section 6(a) (Docket ID. EPA-HQ-OPPT-2016-0231)

Dear Administrator Pruitt:

The U.S. Small Business Administration's (SBA) Office of Advocacy (Advocacy) submits the following comments in response to the Environmental Protection Agency's (EPA) proposed rule, "Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain uses Under TSCA Section 6(a)."¹ Safe chemical use and prevention of hazardous exposure to chemicals are a priority for small businesses to be able to protect both the consumer and their employees. Small businesses, however, have raised concerns with EPA's basis (i.e., risk assessment) for its regulatory proposal for the use of methylene chloride and n-methylpyrrolidone (NMP) in paint and coating removal. Small businesses are also concerned with the agency's consideration of the viable and technically feasible alternatives for methylene chloride and NMP. In addition, small businesses formulators have also raised concerns that the agency did not evaluate the full cost of a potential ban on the use of these chemicals on their products. Finally, small businesses have expressed concerns with the agency's size restriction on the distribution of products with these chemicals. Advocacy urges EPA to carefully address these small business concerns and consider providing regulatory flexibilities for small businesses that allow the agency to achieve its regulatory objective.

The Office of Advocacy

Congress established Advocacy under 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); as such the views expressed by Advocacy do not necessarily

¹ 82 Fed. Reg. 7464 (January 19, 2017).



reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),² as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),³ 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 entities and to consider less burdensome alternatives. EPA is required by the RFA to conduct a SBREFA panel to assess the impact of the proposed rule on small entities,⁴ 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.⁵ 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.⁶

Background

Under Section 6 of the Toxic Substances Control Act (TSCA),⁷ if EPA determines after completing a risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must impose one or more specific requirements so that the chemical substance no longer presents such a risk.⁸ TSCA provides EPA the authority to address the risks resulting from the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal of chemicals.⁹

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act),¹⁰ which recently amended TSCA, allows EPA to publish a proposed rule for a chemical listed in the 2014 update to the TSCA Work Plan for Chemical Assessments, as long as EPA published a completed risk assessment prior to June 22, 2016, the date of enactment of the Lautenberg Act.¹¹ Methylene chloride and NMP are among the chemicals listed in the 2014 update to the TSCA Work Plan for Chemical Risk Assessments. EPA completed its final risk assessment for the use of methylene chloride in paint stripping in August 2014¹² and in March 2015 for NMP,¹³ well before the enactment of the Lautenberg Act.

² 5 U.S.C. §601 et seq.

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

⁴ 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 (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.

⁵ Small Business Jobs Act of 2010 (PL. 111-240) §1601.

⁶ *Id.*

⁷ 15 U.S.C. § 2601 et seq. (1976)

⁸ See 15 U.S.C. § 2605(a).

⁹ *Id.*

¹⁰ Pub. L. 114-182 (June 22, 2016).

¹¹ See 15 U.S.C. § 2625(l)(4).

¹² EPA. TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN: 75-09-2. EPA Document # 740-R1-4003. August 2014. Office of Chemical Safety and Pollution Prevention. Washington, DC. https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptwrkplanra_final.pdf.

In June 2015, EPA formally notified Advocacy of its intent to convene a SBREFA panel for a rulemaking to address the identified risks for both methylene chloride and NMP use in paint stripping. Subsequently, in June 2016, EPA convened a SBREFA panel for a potential rulemaking to address the identified risks for the use of these two chemicals in paint removers.

EPA is proposing a determination of unreasonable risk for the use of these chemicals in paint and coating removal. The proposal includes a prohibition on the manufacture (including import), processing, and distribution in commerce for consumer and commercial uses for both chemicals. The proposed rule also includes a prohibition for these commercial uses of both chemicals, including downstream notification and recordkeeping requirements. The agency's proposal provides a ten-year limited exemption for coating removal uses of both chemicals critical for national security and an exemption for methylene chloride use in commercial furniture refinishing. EPA has also proposed to restrict the distribution of methylene chloride, for the non-prohibited uses, to containers with a volume no less than 55-gallons. The agency has also provided an alternate proposal to regulate NMP, which includes a requirement to establish a worker protection program for commercial use and a limit of 35 percent NMP for processors of paint and coating removal products.

Advocacy Involvement in the Rulemaking Process

Throughout the rule development process Advocacy engaged with EPA and the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) as well as with small businesses and small business representatives, including during the SBREFA Panel process. In addition, following the publication of the proposed rule, Advocacy held a roundtable on April 7, 2017 at which EPA presented its proposal. Advocacy has had extensive contact with various small businesses and small businesses representatives regarding their concerns with the proposal.

Advocacy's comments

I. EPA Should Withdraw the Proposed Rule and Reassess the Methylene Chloride and NMP Use in Paint and Coating Removal as Part of its Ongoing Risk Evaluation for these Chemicals.

The Office of Advocacy urges EPA to withdraw this proposed rule. There is no statutory mandate for this regulation at this time. While it is true that under the Lautenberg Act, the agency *may* regulate methylene chloride and NMP use based on the existing final risk assessments,¹⁴ Congress did not *require* the agency to issue rules based on those risk assessments. Moreover, as required by the Lautenberg Act,¹⁵ EPA recently identified a list of ten high-priority chemicals for which it will begin chemical risk evaluations, and methylene chloride

¹³ EPA. TSCA Work Plan Chemical Risk Assessment N-Methylpyrrolidone: Paint Stripping Use. CASRN: 872-50-5. EPA Document # 740-R1-5002. March 2015. Office of Chemical Safety and Pollution Prevention, Washington, DC. https://www.epa.gov/sites/production/files/2015-11/documents/nmp_ra_3_23_15_final.pdf.

¹⁴ See, 15 U.S.C. § 2625(l)(4).

¹⁵ *Id.* § 2605 (b)(2)(a).

and NMP are among those high-priority chemicals.¹⁶ As a result, in the next three years, EPA will be working to complete a new risk assessment for all uses for both chemicals.

Small business representatives have expressed several concerns with EPA's final risk assessment for methylene chloride. Small business representatives explain that the exposure estimates are unrealistic because the agency relies on data generated before significant changes to the Occupational Safety and Health Administration's (OSHA) permissible exposure limit on methylene chloride and EPA's National Emission Standards Hazardous Air Pollutants (NESHAP) for methylene chloride.¹⁷ Small business representatives contend that relying on exposure data pertinent to periods that precede the effective dates of the two revised standards is misleading.¹⁸ At the time of the proposal, EPA provided supplemental analyses for methylene chloride use in paint strippers, dated July 2016, which includes an examination of additional exposure parameters.¹⁹

Small business representatives have also raised issues with EPA's existing final risk assessment for NMP. Small businesses are concerned that EPA's exposure estimates and risk analysis is based on workplace exposure data and related information and therefore does not characterize consumer-use scenarios where consumers purchase smaller quantities of paint removers on an as-needed basis for limited scale and short-duration uses.²⁰ The final risk assessment for NMP does not identify consumer exposures as a risk.²¹ However, the supplemental analysis completed by EPA in November 2016 does evaluate and identify scenarios of consumer risks.²²

EPA completed the supplemental analyses for both chemicals after the final risk assessments were issued and after the passage of the Lautenberg Act. Risk assessments published after the passage of the Lautenberg Act cannot be the basis of the new regulations.²³ Furthermore, these analyses have not been peer reviewed, although EPA has stated that they will be peer reviewed before the final rule is issued.²⁴ OMB's bulletin on "Final Information Quality Bulletin for Peer Review" requires that important scientific information be peer reviewed.²⁵ In addition, under the Lautenberg Act, TSCA specifically requires that in carrying out actions under Section 6, EPA must use scientific information in a manner consistent with the best available science, and must consider the extent of independent verification or peer review of that information.²⁶

¹⁶ 81 Fed. Reg. 91927 (December 19, 2017).

¹⁷ Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule on Toxic Substance Control Act (TSCA) Section 6(a) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint Removers (September 26, 2016). U.S. Environmental Protection Agency, Office of Policy, Washington, D.C., at 30. [hereinafter Panel Report].

¹⁸ *Id.* Appendix B at 67.

¹⁹ See, EPA. Supplemental Consumer Exposure and Risk Estimation Technical Report for Methylene Chloride in Paint and Coating Removal. July 2016.

²⁰ *Id.* at 30.

²¹ See, *supra* note 13.

²² See, EPA. Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal. November 2016.

²³ See, 15 U.S.C. § 2625(l)(4).

²⁴ 82 Fed. Reg. 7501.

²⁵ 70 Fed. Reg. 2664 (January 14, 2005).

²⁶ 15 USC § 2625(h)(5).

Recommendation

Advocacy recommends that EPA withdraw the proposed rule. Advocacy further recommends that EPA reevaluate the methylene chloride and NMP uses in paint and coating removal as part of the ongoing risk evaluation for both chemicals. Advocacy also recommends that EPA seek peer review on all scientific analyses prior to their use as a basis for any future regulations.

II. EPA Should Reassess the Alternative Products for Availability and for Safe and Effective Use.

After hearing from small businesses, Advocacy believes the cost estimates in EPA's economic analysis underestimate the possible burden of the proposed rule. Multiple assumptions made by EPA were questioned by small businesses. First, small businesses disagree with the effectiveness analysis EPA performed on alternative products.²⁷ EPA estimated that the majority of alternative products have similar efficacies as methylene chloride and NMP.²⁸ However, conversations with small businesses have noted that this is not the case, particularly in the case of methylene chloride, which is faster acting and more effective than almost any alternative, especially for newer coatings. Moreover, during the SBREFA Panel, a small business provided EPA with the results of testing on a variety of coatings on specific substrates.²⁹ The results indicated that chemical solvent alternatives such as toluene, acetone, methanol and benzyl alcohol do not completely remove alkyd or epoxy paints in fewer than four hours and in some cases not at all.³⁰ Comparatively, the results demonstrated that methylene chloride-based paint removal products removed both kinds of coatings from substrates within five minutes on all painted surfaces tested and within fifteen minutes on cured coatings.³¹ There is no indication that the agency took this information into consideration to develop the proposed rule.

Second, small businesses generally disagree with the assumed safety of alternatives in comparison to methylene chloride and NMP. Small businesses pointed out that alternative products have associated workplace and environmental hazards such as flammability and high VOC levels.³² Small businesses also expressed concerns regarding longer exposure for consumers to chemicals in alternative products because they do not perform as quickly as methylene chloride products.³³ Small businesses also note that with an alternative like benzyl alcohol stripper, the hazardous waste generation will increase because a larger quantity is used to reach the same effectiveness as methylene chloride.³⁴

²⁷ EPA (US Environmental Protection Agency). Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal (EPA Docket EPA-HQ-OPPT-2016-0231; RIN 2070-AK07). Office of Pollution, Prevention, and Toxics. Washington, DC., 4-23 [hereinafter Economic Analysis]

²⁸ *Id.* at 4-31, Table 4-19

²⁹ Panel Report at 27-28. See, Appendix B at 63-64.

³⁰ *Id.* Appendix B at 64.

³¹ *Id.*

³² *Id.* 26-27.

³³ *Id.* at 27.

³⁴ *Id.* at Appendix B at 2.

Finally, small businesses disagree with the cost estimates associated with using alternatives. A small business that sells predominately to commercial users stated that over 95 percent of the products sold contain methylene chloride.³⁵ Companies like this sell paint strippers with alternatives; however, they report that they have been trying to promote alternative paint removal products for years but customer acceptance is poor because the alternatives are not as effective as methylene chloride.³⁶ In addition, small businesses state that EPA must do more than merely calculate comparative costs of raw materials, formulating activities, packaging and distribution of current products versus potential alternatives.³⁷ EPA must also assess and consider the costs of buying and using paint and coating removal products.³⁸ EPA's analysis should extend beyond a simple demonstration that it is possible to make and sell a product without methylene chloride.³⁹

Under the amended TSCA, EPA is required to consider whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect.⁴⁰

Recommendation

Advocacy recommends that EPA reassess the alternative products for availability and for safe and effective use. Advocacy also recommends that the agency consider a phase-out or a longer staggered compliance period to assist with a reasonable transition period under TSCA⁴¹ and provide adequate time for innovation instead of a full ban.⁴²

III. EPA Should Take into Consideration All the Costs Associated with Banning Methylene Chloride and NMP on Small Formulators.

Small businesses are concerned with the minimal costs EPA currently estimates for the formulators of methylene chloride and NMP. EPA's analysis assumes that while there may be some reformulation costs, most businesses sell alternative paint stripping products and will replace their sales of methylene chloride and NMP.⁴³ However, alternative products may have lower profit margins than methylene chloride or NMP. Further, assuming that processors can shift production to alternative products, there will be associated transition costs. Changing large product lines can be very costly to small businesses and is currently not considered by EPA. These costs are magnified for businesses that produce large amounts of methylene chloride and NMP and depend on their ongoing sales to stay viable. A disruption in a product line, including the costs of changing production, can produce a large economic shock to small formulators. Small formulators specifically pointed this out to EPA during the SBREFA panel, stating that a

³⁵ Panel Report at Appendix B at 14.

³⁶ *Id.* at 30.

³⁷ *Id.* at 27.

³⁸ *Id.* at Appendix B at 64-65.

³⁹ *Id.*

⁴⁰ 15 U.S.C. § 2605(c)(2)(C).

⁴¹ *Id.* at § 2605(d)(1)(E).

⁴² *Id.* at 2605(d)(1). TSCA allows EPA up to five years to require compliance. *Id.*

⁴³ Economic Analysis at 4-41 and 4-45 - 4-46.

ban on these chemicals will cause entire product lines to disappear since there are no drop-in replacements for methylene chloride.⁴⁴

Recommendation

Advocacy recommends that the agency take into consideration and account for all the costs that may be incurred by small formulators under the proposed regulation.

IV. EPA Should Adopt the Least Restrictive Proposal to Allow for NMP Use in Paint Removal Products.

In addition to a ban on the commercial and consumer use and production of NMP for use in paint removal products, EPA is co-proposing a second option.⁴⁵ The second option requires reformulation of products (NMP not to exceed 35 percent), glove testing (for each specific formulation), labeling (including the identification of appropriate gloves), and providing worker protection information to commercial users.⁴⁶ This alternate proposal provides regulatory flexibility and will also address the agency's unreasonable risk determination for NMP. Regarding the costs associated with this option, the decision to invest in complying with the additional regulations to be able to use NMP in product formulations or to forgo the production of NMP-based paint removal products should be up to the businesses.

Recommendation

Advocacy recommends that EPA adopt the least restrictive co-proposal to allow for the use of NMP in paint removal products.

V. EPA Should Not Impose Container Size Restrictions on the Use of Methylene Chloride.

EPA proposes to require that any paint and coating removal product containing methylene chloride must be distributed in containers with a volume of no less than 55 gallons.⁴⁷ Small businesses have expressed concerns with this restriction because most use 5-gallon or smaller size container. Specifically, small contractors contend that the use of 1-gallon container is critical in their work.⁴⁸ Small businesses pointed out that the restriction to 55-gallon drums is counterproductive to the objective of reducing risk of exposure because an additional hazard may be created for the small business end user when transferring product to a secondary (smaller) container.⁴⁹ Small businesses also stated that purchasing large quantities of methylene chloride or NMP as would be required under 55-gallon container may not be feasible for smaller

⁴⁴ Panel Report at 26.

⁴⁵ 82 Fed. Reg. at 7507.

⁴⁶ *Id.*

⁴⁷ EPA provides an exemption from this requirement for the Department of Defense. 82 Fed. Reg. at 7492.

⁴⁸ Panel Report at 23 and 25.

⁴⁹ *Id.* at 21.

budgets.⁵⁰ Small businesses added that packaging in 55-gallon quantities is not practical for all facilities.⁵¹ For example, a 55-gallon drum of methylene chloride can weigh up to 600 pounds.⁵²

Recommendation

Advocacy recommends that the agency eliminate any restriction on the container size of these chemicals because it will disproportionately affect small businesses.

Conclusion

Advocacy suggests that EPA take back the rule and include the analysis of these uses as part of its ongoing efforts to do risk evaluations for both methylene chloride and NMP under the amended TSCA. Alternatively, if the agency decides to go forward based on the existing risk assessment, Advocacy suggests that EPA reassess the viability and technical feasibility of the available alternatives, reevaluate the costs to formulators, and eliminate the restriction on the container size for these chemical products. And finally, the agency should adopt the least restrictive co-proposal to allow for the use of NMP in paint and coating removal products. Advocacy urges EPA to give full consideration to the above issues and recommendations. We look forward to working with you to reduce the regulatory burden on small businesses.

If you have any questions or require additional information please contact me or Assistant Chief Counsel Tayyaba Waqar at (202) 205-6970 or by email at twaqar@sba.gov.

Sincerely,



Major L. Clark III
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Copy to: Dominic J. Mancini
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⁵⁰ *Id.*

⁵¹ Panel Report at 26.

⁵² *Id.* at Appendix B at 5.