

March 15, 2013

BY ELECTRONIC MAIL

Ms. Wendy Cleland-Hamnett
Director, Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Comments on EPA's Draft Toxic Substances Control Act Workplan Chemical Risk Assessments of Methylene Chloride, N-Methylpyrrolidone and Trichloroethylene

Dear Ms. Cleland-Hamnett,

The U.S. Small Business Administration's Office of Advocacy (Advocacy) submits the following comments on the Environmental Protection Agency's (EPA) Draft Toxic Substances Control Act (TSCA) Workplan Chemical Risk Assessments (Risk Assessment) of Methylene Chloride (DCM), N-Methylpyrrolidone (NMP) and Trichloroethylene (TCE). Advocacy supports EPA's efforts to enhance EPA's existing chemicals management program and recognizes that better scientific analysis of the risks to human health and the environment benefit the whole of society. However, Advocacy is concerned with EPA's focus on "small commercial shops"¹ in the Risk Assessments of DCM, NMP and TCE, including the lack of specific data from these settings and the assumption that employee exposure at small commercial shops is less well-controlled and monitored than exposures from large-scale industrial operations. Because EPA intends to use the Risk Assessments "to help focus and direct the activities of the Existing Chemicals Program over the next several years"², Advocacy anticipates that such activities will include rulemakings that would be subject to the Regulatory Flexibility Act (RFA). Therefore, it is essential these Risk Assessments accurately model small commercial shop use of, and employee exposure to, the chemicals in order to ensure that EPA has sufficient information to develop regulatory alternatives that minimize the impact on small entities while fulfilling the objectives of TSCA.

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.³ The Regulatory Flexibility Act

¹ For the purpose of the assessments, EPA defines a "small commercial shop" as one that employs fewer than 10 workers; the remaining facilities were considered large facilities or were unassigned and were not considered in this assessment.

² Retrieved from <http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html>.

³ 15 U.S.C. § 634a, *et. seq.*

(RFA),⁴ as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA),⁵ 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,”⁶ EPA is required by the RFA to conduct a Small Business Advocacy Review (SBAR) Panel to assess the impact of the proposed rule on small entities,⁷ and to consider less burdensome alternatives.

The Risk Assessments

Supporting the Risk Assessments’ primary focus on “small commercial shops” requires adequate data. Advocacy agrees it is reasonable to consider exposure assessments in small business settings separately from those in large businesses and in consumer settings. However, if the Agency chooses to do so, the exposure assessments should be grounded in available data, and not based on simplifying assumptions that lack an analytical basis.

Advocacy has not found adequate data in the Risk Assessments of NMP, DCM and TCE to support the Agency’s focus on small commercial shops. Advocacy is particularly concerned with the focus on small commercial shops in the NMP Risk Assessment. EPA evaluated NMP for its use in paint stripper by small commercial shops. The Risk Assessment contains little actual data on exposure at small commercial shops on which to base a robust analysis. First, EPA relied on modeling for dermal exposure and noted that the Agency “found no published data to assess dermal exposures to small commercial shop workers.”⁸ In the absence of data, the dermal exposure analysis “uses a more conservative or ‘worst case’ assumption ... to assessing the potential risks of concern.”⁹ Second, EPA relied on limited exposure data based on observational studies to determine inhalation exposure. EPA noted “there were few studies available that provided enough useful data or background information to develop statistical distributions of exposure for the populations.”¹⁰ Third, to support the Agency’s decision to focus on small commercial shops, EPA explained that it believes exposures that may occur in the small shop settings are generally less well-controlled and poorly monitored. For example, EPA relied on the assumption that “small commercial shop workers did not wear protective gloves while working with NMP-based paint stripping products.”¹¹ Advocacy, in its outreach with small remodelers, painters and decorators, found this assumption to be incorrect. Neither EPA’s assumptions on small commercial shop operation and safety, nor exposure modeling, are supported by data from small commercial shops.

⁴ 5 U.S.C. § 601, *et. seq.*

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

⁶ *See* 5 U.S.C. § 609(a), (b).

⁷ 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.

⁸ U.S. EPA (2012). TSCA Workplan Chemical Risk Assessment for N-Methylpyrrolidone: Paint Stripping Use. U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Washington, D.C. Retrieved from http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Workplan_Chemical_Risk_Assessment_of_NMP.pdf, 26.

⁹ *Id.* at 26.

¹⁰ *Id.* at 28.

¹¹ *Id.* at 26.

Similar concerns with the DCM Risk Assessment have been raised by small businesses. First, as with the NMP Risk Assessment, the DCM Risk Assessment focuses on the assumed lack of best practices and safety in small commercial shops. Second, EPA models worker exposure in the DCM and TCE Risk Assessments for small commercial shops without sufficient data because the vast majority of the data available is industry-wide, not specific to small shops. For example, the DCM modeling is based on NAICS facility and worker data across various industries, without breaking the information down by facility size and without taking into account how small shops differ from large facilities. If EPA is going to rely on facility size distinctions in its Risk Assessments, then EPA should either gather more specific data related to facility size or break down the data set by size of facility before finalizing the Risk Assessments.

Conclusion

Advocacy supports EPA's efforts to enhance the Agency's existing chemicals management program. Modeling exposure to chemicals based on different user groups, such as large facilities, small facilities and consumers, is an important regulatory tool and provides for regulatory flexibility. Advocacy understands that EPA is often working with limited data. However, in the absence of sufficient data to break down the data, EPA should not single out small businesses. Because these Risk Assessments will influence future EPA actions, and in order to ensure EPA has sufficient and accurate information to develop regulatory alternatives that minimize the impact of regulations on small entities, it is essential the Risk Assessments accurately model small commercial shop use and exposure for these chemicals. Advocacy would be pleased to put EPA in contact with small businesses that use products containing DCM, NMP and TCE. We look forward to continuing to work with EPA and advising EPA on the concerns of our small business stakeholders.

If my office can be of any further assistance, please contact me or Sarah Bresolin Silver at (202) 205-6790 or sarah.bresolin@sba.gov.

Sincerely,

/s/

Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy

/s/

Sarah Bresolin Silver
Assistant Chief Counsel
Office of Advocacy