May 19, 2017

Ms. Ana Corado
Chemical Control Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW.
Washington, DC 20460–0001
ATTN: Docket ID No. EPA-HQ-OPPT-2016-0231

RE: Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA §6(a) (Submitted Electronically at regulations.gov)

Dear Ms. Corado:

The Association of Global Automakers, Inc.[1] (Global Automakers) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) proposed rule, "Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA §6(a)" (82 FR764-7533, January 19, 2017). Global Automakers is providing this comment to offer best practices for EPA to consider as it proceeds through the rulemaking process in the implementation of the new provisions added by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016 (LCSA or The Act). It is crucial that the implementation of these new provisions be consistent with the intent and regulatory requirements of LCSA. EPA's application of these new provisions could set a precedent for future rulemakings under TSCA §6(a).

In this rule, EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer and for most types of commercial paint and coating removal uses. EPA is also proposing to prohibit the use of methylene chloride for commercial paint and coating removal in a number of specified sectors, including automotive refinishing, and would require manufacturers (including importers), processors, and distributors (except for retailers), of methylene chloride for any use to provide downstream notification of these requirements and prohibitions throughout the supply chain and to require limited recordkeeping.

[1] The Association of Global Automakers represents international motor vehicle manufacturers, original equipment suppliers, and other automotive-related trade associations. Global Automakers works with industry leaders, legislators, regulators, and other stakeholders in the United States to create public policies that improve motor vehicle safety, encourage technological innovation, and protect our planet. Our goal is to foster an open and competitive automotive marketplace that encourages investment, job growth, and development of vehicles that can enhance Americans' quality of life. Our members' share of sales and production in the United States is nearly 45 percent and growing. For more information, visit www.globalautomakers.org.

EPA is proposing two different risk management options for N-Methylpyrrolidone (NMP):

- Option 1 would prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all uses in consumer and commercial paint and coating removal, with exemptions for certain national security uses. Additionally, Option 1 would require manufacturers (including importers), processors, and distributors, except for retailers, of any NMP use to provide downstream notification of these prohibitions throughout the supply chain, and require limited recordkeeping.
- Option 2 for NMP would require product reformulation to limit the concentration of NMP in paint and coating removal products, relabeling of products to provide additional information to consumers, occupational dermal and respiratory protection programs for commercial use of NMP in paint and coating removal, downstream notification when distributing NMP for other uses, and limited recordkeeping.

Global Automakers' members have been phasing out the use of older chemistries such as methylene chloride and NMP, and while this rule may not directly apply to our members, Global Automakers is providing these comments in order to offer best practices and important, precedent-setting considerations related to the implementation of the LCSA. Global Automakers' comments focus on the implementation of five major components of the proposal:

1. Compliance with the Requirements of TSCA §6
2. Compliance with the Requirements of TSCA §26
3. Conditions of Use
4. Lead-Time Setting
5. Downstream Notification Requirements

1. Compliance with the Requirements of TSCA §6

EPA may issue rules under TSCA §6(a) that are "consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA" for chemicals that are included in the 2014 update to the TSCA Work Plan for Chemical Assessments and that have a completed risk assessment.[2] The Act further requires that EPA must issue these regulations in accordance with additional requirements laid out in TSCA §6(c)(2)(A), including assessing the economic consequences of the rule and presenting costs and benefits of the proposed regulatory approach and all potential options.[3] Methylene chloride and NMP are included in the 2014 TSCA Work

[2] 15 U.S.C. § 2625 (l)(4).
[3] 15 U.S.C. § 2605(c)(2)(A).

Plan Update. Although both chemicals have completed risk assessments published prior to the enactment of LCSA, this regulatory proposal is taking place after LCSA was enacted and therefore should meet the intent and requirements of LCSA.

In addition, when identifying alternatives to the chemical subject to a proposed regulation, §6(c)(2)(C) of The Act requires EPA to consider "whether technically and economically feasible alternatives that benefit health or the environment…will be reasonably available as a substitute when the proposed prohibition or restriction takes effect."[4]

Global Automakers is concerned that EPA has not fully assessed all of the criteria, as required by TSCA §6(c)(2)(A). EPA should provide a greater level of detail and analysis as it relates to both risk assessment and economic feasibility than has been prepared for this proposal. Based on Global Automakers' review of the economic analysis used in support of the proposed rule, we believe that EPA has not met the threshold of analysis and transparency of decision logic directed by The Act.

Adequate information to complete a reliable and transparent economic analysis is a key part of the TSCA assessment under The Act. EPA should use its authority to gather a comprehensive set of information. For example, throughout the proposal, EPA requests additional information related to basic components of an alternatives analysis and an economic analysis. Specific to NMP, "EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies."[5] EPA also acknowledges uncertainties in the benefits calculations for methylene chloride that undermine the credibility of EPA's final economic impacts determination, stating that "[u]ncertainties in benefit calculations arose from EPA's use of a forecast from an industry expert to estimate the categories of alternatives that users might choose to adopt."[6]

Yet, EPA still proposes action on these uses of NMP and methylene chloride. In contrast, EPA declined to regulate methylene chloride uses in furniture refinishing, citing a lack of information that would inhibit EPA's ability to assess the economic consequences of any proposed action:

> EPA is at this time seeking additional information to inform its consideration of the reasonably ascertainable economic consequences of an action that would address the risks of commercial furniture refinishing so that they are no longer unreasonable, as required under TSCA §6(c)(2)(A)(iv).[7]

[4] 15 U.S.C. § 2605(c)(2)(C).
[5] 82 FR at 7481, January 19, 2017.
[6] 82 FR at 7491, January 19, 2017.
[7] 82 FR at 7491, January 19, 2017.

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Similar to the logic used to determine that furniture refinishing uses would not be regulated, EPA should reassess whether it has adequate information to complete a reliable and transparent economic analysis for methylene chloride and NMP, and use its information-gathering authorities to obtain the necessary information.

In response to EPA's questions on the appropriateness of "its decision to pursue risk management for specific conditions of use of methylene chloride while preparing to conduct a risk evaluation of remaining conditions of use of methylene chloride under TSCA §6(b)," Global Automakers believes that EPA should delay further work on this proposal until it has current, accurate data on all uses and potential economic impacts.[8]

TSCA §6(c)(2)(C) requires EPA to determine "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or restriction takes effect."[9] The alternatives analyses that EPA has prepared to support this proposal does not fulfill this requirement. It is not clear that EPA has done its due diligence in identifying viable substitutes for all methylene chloride and NMP paint and coating removal uses.

There are also a number of specific uncertainties in the alternatives analysis prepared by EPA that raise concerns for Global Automakers' members. Two specific statements in the proposal reflect these uncertainties. The first statement— "there may be costs associated with these alternatives that are not adequately accounted for in the analysis"— acknowledges that EPA has not fully studied all the costs associated with the identified alternatives.[10] It is incumbent on EPA to ensure that all costs associated with this proposal are reflected in the associated alternatives analysis. An economic analysis that does not reflect all associated costs is misleading and will lead to an underestimation of costs to be borne by the regulated community. The second statement— "[w]hile there are no products or methods that have comparable cancer or lethal risks, these substitute products and alternative methods do present hazards"— raises concerns for Global Automakers' members related to the unintended consequences of regrettable substitution.[11] It is imperative for EPA to identify alternatives that offer some degree of certainty for the regulated community. To accentuate this point, NMP has served as a substitute for many regulated uses of methylene chloride to date, and EPA is now proposing to ban its use in several of those applications.

[8] 82 FR at 7468, January 19, 2017.
[9] 15 U.S.C. § 2605(c)(2)(C).
[10] 82 FR at 7491, January 19, 2017.
[11] 82 FR at 7491, January 19, 2017.

While EPA has made clear that there are a number of national security uses of NMP for which there are currently no substitutes, EPA's proposal is silent on the issue of critical needs for the rest of the regulated community. Global Automakers believes that EPA must address any critical uses or critical needs when applying the requirements of TSCA §6(g).

2. Compliance with the Requirements of TSCA §26

TSCA §26(h) requires that EPA "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed in a manner consistent with the best available science."[12] Additionally, TSCA §26(k) requires that EPA "shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator."[13]

Global Automakers is concerned that EPA has not done its due diligence in collecting information regarding conditions of use that are "reasonably available to the Administrator." In its proposed rule, EPA uses information that is not only limited in scope but also outdated. For example, EPA used 2012 Chemical Data Reporting information to estimate the pounds of methylene chloride produced or imported into the United States.[14] Data that is five years out of date should not be used to support rulemakings that will have a significant impact on the economy. EPA also relied on 2012 and 2014 Toxics Release Inventory (TRI) data to ascertain the number of methylene chloride and NMP users. As acknowledged by EPA in its proposal to regulate TCE for vapor degreasing, "TRI data does not represent all of the facilities manufacturing, processing, and/or using [a chemical] because only certain industries and types of facilities are required to report.[15]

Using outdated and limited data sources introduces a high degree of uncertainty into EPA's economic analysis and has the potential to significantly skew the estimated impacts of the rule. Using this information as the basis to determine the extent of this rule's impact, the conditions of use, and potential exposure scenarios does not meet the requirement to "consider information that is reasonable available" or to use "best available science." EPA has numerous, available options for collecting relevant and timely information to more fully inform its rulemakings. EPA must use more complete data sources as the basis for its determinations under TSCA.

[12] 15 U.S.C. § 2625(h).
[13] 15 U.S.C. § 2625(k).
[14] 82 FR at 7468, January 19, 2017.
[15] 82 FR at 7435, January 19, 2017.

3. Conditions of Use

Global Automakers is also concerned about EPA's apparent decision to use TSCA to address "conditions of use" that are currently regulated under other federal statutes. EPA is using TSCA to address what it believes to be inadequacies in other federal statutes. The proposal states:

> Methylene chloride has been the subject of U.S. federal regulations by EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). EPA and other agencies have taken actions to address the serious human health risks from specific sources and routes of methylene chloride exposure, but none of these actions sufficiently mitigate the risks that EPA is proposing to address under TSCA §6(a).[16]

Global Automakers believes that EPA has adopted a very expansive interpretation of its statutory authorities regarding "conditions of use" and its authorities under TSCA §9.

The LCSA removed the "least burdensome" provision from the TSCA statute, which may appear to make it more flexible than some other statutes. However, that is not a justification for using TSCA when other statutes should take precedence. For example, EPA states in its proposal:

> …a consumer product safety rule under the Consumer Product Safety Act (CPSA) must impose "the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated."[17]

EPA appears to be using TSCA to circumvent the "least burdensome" requirement of the CPSA.

Global Automakers has the same concern that EPA is using TSCA as a surrogate for the Occupational Safety and Health Act (OSHA). In 2014, OSHA issued a notice, "Chemical Management and Permissible Exposure Limits (PELs)" specifically requesting public engagement on the issue of how to develop more appropriate PELs for chemicals of concern.[18] OSHA received over 75 comments on how to better develop PELs. EPA should recognize that establishing PELs falls under the authority and rulemaking procedures of OSHA. Global Automakers does not support the use of TSCA as a surrogate for implementation of the CPSA, OSHA, or other federal statutes where another agency is perceived to have failed to take action.

4. Lead-Time Setting

[16] FR 82 at 7469, January 19, 2017.
[17] FR 82 at 7521, January 19, 2017.
[18] FR 79 at 61383, October 10, 2014.

TSCA §6(c)(3)(d) provides EPA with flexibility for determining workable effective dates for rulemakings. Global Automakers acknowledges that this proposed rule requests comment on effective dates. Global Automakers would also like to reinforce the need to work with the impacted sectors to determine a workable transition period not only for this proposal, but for future proposals under TSCA §6(a). Global Automakers is providing this comment in terms of best practices that we would like to see with other TSCA-related rulemakings going forward. This needs to be an inclusive process that reaches out to all impacted sectors. EPA should use not only its current approach of holding meetings with certain stakeholders, but should also include a more comprehensive engagement process that allows fuller participation by downstream users as early in the process as possible.

5. Downstream Notification Requirements

EPA's proposal includes a requirement for "manufacturers, processors, and distributors, except for retailers of Methylene Chloride and NMP for any use, to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping." This rulemaking could set a precedent for this regulatory option under The Act. Thus, it is critical that EPA be precise in identifying exactly who will be responsible for these notifications and where the burden (costs) will be borne. The rule should make clear the content and the mechanism of notification required and what the hierarchy for notification shall be. For example, what responsibility do importers have for downstream notification? EPA also needs to better estimate the costs as well as the feasibility of downstream notification requirements. EPA acknowledges the uncertainties in their assessment of these costs and these uncertainties can be removed if EPA will collect current and accurate data:

> There are uncertainties due to the estimates of the number of affected commercial and consumer users, and for numbers of processors and distributors of methylene chloride-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records.[19]

Additional specific issues that should be addressed include how these requirements relate to complex durable goods and how these requirements work in a global market.

In summary, Global Automakers believes that this proposal and its supporting documents do not meet the requirements of TSCA §6(c)(2)(A), §6(c)(2)(C), §26(h), and §26(k). Global Automakers believes it is critical for EPA to implement TSCA rulemakings consistent with the intent and regulatory requirements of LCSA. This rulemaking is one of the first, along with two TCE proposals, that could set a precedent in implementation of the LSCA provisions, and it is not clear that EPA has given full

[19] 82 FR at 7491, January 19, 2017.

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consideration to these new provisions.[20] Global Automakers believes that additional action is needed to ensure successful implementation of the Act through this rulemaking.

We appreciate the opportunity to provide these comments and welcome the opportunity to provide additional information to assist in the successful implementation of TSCA. In the event of questions regarding these comments, please contact Amandine Muskus, Manager, Environment & Energy, at (202) 650-5555 or amuskus@globalautomakers.org.

Sincerely,

Julia M. Rege
Director, Environment & Energy

[20] Global Automakers has submitted similar comments on the trichloroethylene (TCE) proposal on dry cleaning uses (81 FR 91592, December 16, 2016). *See* Global Automakers comments at EPA-HQ-OPPT-2016-0163-0166. Global Automakers will also submit similar comments on the TCE proposal on vapor degreasing uses (82 FR 7432, January 19, 2017); these comments are due April 19, 2017. Like our comments on methylene chloride and NMP, Global Automakers' comments on the two TCE proposals are based on best practices and important precedent-setting provisions related to the implementation of the LSCA.

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