AmericanCoatings
ASSOCIATION℠

Jan 21, 2020

Dr. Stan Barone
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Submitted via eRulemaking Portal: www.regulations.gov
Re: Docket No. EPA-HQ-OPPT-2019-0236

Dear Dr. Barone,

The American Coatings Association ("ACA")[1] appreciates the opportunity to comment on EPA's Draft Risk Evaluation for N-Methylpyrrolidone (NMP), required by the *Frank R. Lautenberg Chemical Safety for the 21st Century Act* (*Lautenberg Act*). We are committed to working with EPA to help ensure accurate risk evaluations under the amended Toxic Substances Control Act (TSCA).

ACA represents 90% of the paint and coatings industry, including downstream users (or processors) of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture paints, coatings, sealants and adhesives whose manufacturing processes or products may be affected by the outcome of EPA's risk evaluation for NMP. As such, our members are concerned about EPA's process for chemical risk evaluations. ACA is eager to assist EPA in developing an effective system for chemical risk evaluations with successful implementation of the *Lautenberg Act's* mandates.

ACA appreciates EPA's willingness to interact with stakeholders during this process. ACA understands that implementation of the *Lautenberg Act* presents several challenges, and

[1] ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services.

we commend EPA on the solutions it has offered thus far. We are optimistic that through continued involvement with the public and stakeholder community, EPA will successfully implement a stronger, federal chemicals management program for years to come.

ACA and its members respectfully submit the following comments.

I. The *Lautenberg Act's* Requirements for EPA Risk Evaluations

Amendments to TSCA under the *Lautenberg Act* establish considerations and quality requirements for EPA risk evaluations. EPA further explains requirements and process in its risk evaluation rules at 40 CFR 702, Subpart B. Under the *Lautenberg Act*, EPA must conduct risk evaluations using the *best available science*[2] (TSCA §26(h)) with determinations based on the "weight of scientific evidence."[3] (TSCA §26(h)). In the statute, congress further requires EPA integrate and assess information about hazards and exposures, while considering the likely duration, intensity, frequency and number of exposures under the conditions of use of a chemical. (TSCA §6(b)(4)(F)).

ACA recognizes that EPA is charged with a formidable task and is committed to meeting the deadlines imposed by the *Lautenberg Act*. ACA believes that by integrating its comments below, EPA can develop more accurate exposure assessments to meet the quality requirements for risk evaluations of the *Lautenberg Act* and EPA's risk evaluation rule.

II. EPA's Findings of Unreasonable Risk Do Not Provide Adequate Certainty and Parameters for Risk Mitigation

[2] *Best available science* means science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable:
(1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
(2) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
(3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
(4) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
(5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.
(40 CFR 702.33)

[3] *Weight of scientific evidence* means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.
(40 CFR 702.33)

ACA is concerned that EPA will not be able to prescribe adequate risk mitigation measures tailored to a condition of use because of inconsistencies and vaguely supported findings. EPA does not have a broad set of data for several conditions of use, relying on one study, Exxon 1991[4], to reach conclusions of unreasonable risk, while assigning a confidence level of medium or low. Nonetheless, EPA has reached a conclusion of "unreasonable risk" for several uses relevant to paints, coatings, sealants and adhesives, including:

- *Processing – Incorporation into formulation, mixture or reaction product* (Draft NMP Risk Evaluation, p. 221)
- *Application of Paints, Coatings, Sealants and Adhesives – spray, roll / curtain, brush and dip application* (Draft NMP Risk Evaluation, p. 224)
- *Industrial and Commercial Use – Paint and Coating Removers* (Draft Risk Evaluation, p. 233)
- *Laboratory Chemicals* (Draft Risk Evaluation, p. 240)
- *Paint and Coating Removers, Consumer Use* (Draft Risk Evaluation, p. 263)

EPA's finding of unreasonable risk will be used to develop risk mitigation measures after EPA finalizes its risk evaluation in Summer 2020. Yet, for several conditions of use, EPA has not identified, to a high degree of certainty, conditions causing risk.

In some cases, EPA reaches conclusions using the "high end" scenario, assuming eight hours of exposure, typically not reflective of actual exposure in industry. Similarly, in some cases the "central tendency" may underestimate or overestimate exposure. Without additional data, EPA cannot assess how its models relate to *actual* workplace exposure.

ACA applauds EPA's readiness to recognize deficiencies in data and limitations of conclusions, as specified for each condition of use in Section 4 of its Draft Risk Evaluation for NMP. ACA further details concerns with EPA's evaluation process below, to suggest that a) EPA gather additional data or provide further explanation related to identified issues in the final risk evaluation; and/or b) recognize limitations during risk mitigation so as not prescribe unnecessarily restrictive and unjustified control measures, including banning NMP or setting unreasonable *de minimis* values for the uses below.

ACA notes the following limitations in EPA's evaluation by condition of use:

a. *Processing – Incorporation into formulation, mixture or reaction product*

[4] *Multigeneration Rat Reproduction Study with N-Methylpyrrolidone, Project Number 236535*, Exxon Mobil Biomedical Sciences, 1991 (cited as "Exxon 1991" in EPA's Draft Risk Evaluation), available online at: https://www.epa.gov/sites/production/files/2019-12/documents/nmp_exxon_1991_multigenerational_reproductive_study_0.pdf

EPA notes that its evaluation considers the high end scenario only, since it does not have information about the central tendency, due to limitations in CDR data. This may lead to inaccuracies in duration of exposure. Exposure duration may not reflect actual worker activities and all worker activities. EPA also notes that it does not have accurate data about emissions factors, to estimate fugitive emissions during loading and unloading. EPA relies on one study (Exxon 1991)[5] for 7 data points used for emissions estimates.

With this limited data, EPA reaches a conclusion of unreasonable risk of injury to worker health, from chronic inhalation and dermal exposure during drum unloading and loading into shipping containers. EPA, however, issues an incongruous conclusion for *manufacture* of NMP for the same activity — loading and unloading of containers — even though concentration of NMP during manufacture would typically be higher than during processing in formulations. Nonetheless, EPA reaches a conclusion of no unreasonable risk for *manufacture of NMP* while finding unreasonable risk to workers when *processing in formulations*. In both cases, EPA's analysis is based on loading and unloading. Similarly, EPA reaches conclusions of no unreasonable risk for *import and repackaging of NMP* and *chemical processing, excluding formulation*, where workers would be dealing with an NMP product in higher concentrations of NMP then typically handled by formulators.

[5] *Multigeneration Rat Reproduction Study with N-Methylpyrrolidone, Project Number 236535*, Exxon Mobil Biomedical Sciences, 1991 (cited as "Exxon 1991" in EPA's Draft Risk Evaluation), available online at: https://www.epa.gov/sites/production/files/2019-12/documents/nmp_exxon_1991_multigenerational_reproductive_study_0.pdf

As noted in Table 2-66 (Draft NMP Risk Evaluation, p. 131), EPA assumes higher air concentration and exposure times at the high end scenario for *incorporation into a formulation*, than when *manufacturing, repackaging or processing* NMP:

Activity	Scenario	Air Concentration (mg / m3)	Duration (hr.)
Incorporation into formulation, mixture or reaction product	Central tendency (drum unloading)	1.65	0.36
	High-end (maintenance, bottling, shipping, loading)	12.8	8
Manufacturing NMP	Central tendency (Bulk container loading)	0.76	0.5
	High-end (drum loading)	5.85	2.06
Repackaging NMP	Central tendency (Bulk container unloading)	0.76	0.5
	High-end (drum unloading)	5.85	2.06
Chemical Processing, Excluding Formulation	Central tendency (Drum unloading)	1.65	0.36
	High-end (Drum unloading)	5.85	0.36

Conditions during all four of these activities are largely similar. In each of the four activities, loading and unloading is typically conducted using automated systems. (EPA NMP Scoping Document, p. 59). EPA assumes saturation of transport piping and estimates fugitive emissions based on concentration values.

EPA's finding of unreasonable risk for *incorporation into a formulation* is due to estimated values for the high-end scenario (shaded above) and the time duration. EPA states it uses the upper end of concentration ranges manufacturers reported during CDR reporting (Draft Risk Evaluation, p. 222). This is not reflective of ***actual*** concentration during formulation of paint, coatings, sealants and adhesives. EPA also notes that exposure duration — noted at 8 hours for the high-end scenario for this use — is based on monitoring data, although the duration is not an adequate estimate for all relevant worker activities. (Draft Risk Evaluation, p. 222).

ACA requests that EPA address these discrepancies and/or supplement this draft evaluation with additional information and data points, to the extent possible. ACA

believes EPA must reach a higher level of accuracy and confidence to develop effective and feasible risk mitigation measures and to meet TSCA's requirement of using the *best available science*.

b) Reliance on "high end" scenario does not reflect worker exposure as it relates to several conditions of use

EPA proposes a finding of unreasonable risk based on chronic exposures at the "high end" scenario, not the "central tendency," assuming glove use with a protection factor of 10. EPA reaches this conclusion for several conditions of use related to paints, coatings, sealants and adhesives, as listed below:

- *Processing – Incorporation into formulation, mixture or reaction product* (Draft NMP Risk Evaluation, p. 221)
- *Application of Paints, Coatings, Sealants and Adhesives – spray, roll / curtain, brush and dip application (*Draft NMP Risk Evaluation, p. 224)
- *Industrial and Commercial Use – Paint and Coating Removers* (Draft Risk Evaluation, p. 233)
- *Laboratory Chemicals* (Draft Risk Evaluation, p. 240)

The high-end scenario may not represent actual exposure in the workplace. EPA used monitoring data to develop an 8-hour time weighted average for the high-end exposure scenario. Modeling for this high-end scenario indicates that exposure does not meet MOE threshold, indicating unreasonable risk. The 8-hour period does not reflect actual exposure times of a worker during a shift. As a result, the conclusion of unreasonable risk does not necessarily mean that workers are exposed to a health risk in the workplace. ACA requests that EPA use actual workplace exposure data or exposure times for these conditions of use or recognize the limitations of its approach when considering risk mitigation measures, by not imposing overly restrictive risk mitigation measures or a ban for these conditions of use.

c) Reliance on One Study Compromises Quality

ACA believes that the quality of EPA's evaluation can be enhanced by including relevant concentrations and exposure times from multiple sources and monitoring data, where possible. To evaluate all conditions of use listed above, EPA relied on one, non-peer reviewed study. This source is:

> *Multigeneration Rat Reproduction Study with N-Methylpyrrolidone, Project Number 236535*, Exxon Mobil Biomedical Sciences, 1991 (cited as "Exxon 1991" in EPA's Draft Risk Evaluation), available online at: https://www.epa.gov/sites/production/files/2019-12/documents/nmp_exxon_1991_multigenerational_reproductive_study_0.pdf.

ACA recognizes that EPA may not have access to additional data. ACA would like to coordinate with EPA on filling in the data gaps, to the extent possible.

Due to limitations with EPA's one study approach as noted above, its unlikely that the draft evaluation is based on the *best available science*, as required by TSCA §26(h). Best available science, "involves the *use of supporting studies* conducted in accordance with sound and objective science practices, including, *when available, peer reviewed science* and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." (40 CFR 702.33, *italics added*). The lack of corroborating, peer-reviewed data here calls EPA's conclusions into question.

III. EPA Should Consider Use of PPE During Risk Evaluation and Risk Mitigation

ACA supports EPA's approach to considering use of Personal Protective Equipment (PPE) when conducting a risk evaluation. EPA's consideration of exposure both with and without PPE provides useful information for risk mitigation. ACA also supports EPA's use of Safety Data Sheets to identify PPE typically used when handling NMP.

ACA would further suggest that EPA not assume all companies use the same level of PPE, absent a rule requiring specific PPE. Assumptions about PPE use are valid to evaluate worker exposure; but those assumptions may not be valid when proposing risk mitigation measures. Since EPA will initiate risk mitigation in Summer 2020, ACA recommends EPA consider requiring PPE where it has issued a finding of no unreasonable risk based on use of PPE.

The U.S. Occupational Safety and Health Administration (OSHA) does not have a specific standard requiring PPE for NMP, nor does an EPA Significant New Use Rule (SNUR) address the issue. While many employers implement PPE requirements when handling NMP to comply with the general duty to provide a safe workplace, not all businesses have the capacity to identify and implement the necessary level of protection. EPA can assist such businesses by requiring PPE that mitigates risk to "no unreasonable risk."

IV. EPA's Systematic Review Process May Exclude Relevant Information

As noted above, ACA is concerned that EPA does not have enough data about conditions of use relevant to processing into formulation, application, use and laboratory use of paints, coatings, sealants and adhesives. Moreover, EPA may have inadvertently excluded relevant studies during application of its systematic review process. During systematic review of data sources for NMP, EPA excluded 39 studies. (NMP Draft Risk Evaluation, p. 49). Since EPA has not identified or made these studies

available, ACA is uncertain whether these contained useful information related to occupational or consumer exposure during manufacture and/or use of paints, coatings, sealants and adhesives.

In its NMP risk evaluation, EPA recognizes that the quality of data in excluded studies is acceptable for risk assessment, but EPA excluded studies based on its hierarchy of preferences (NMP Draft Risk Evaluation, caption to Fig. 1-6, p. 49). ACA suggests that EPA make excluded studies available or at a minimum provide a list of excluded studies with an explanation of how EPA applies its hierarchy of preferences to each study.

ACA is also concerned that the systematic review process is generally flawed. EPA may continue to inadvertently exclude useful information from review in future risk evaluations. This problem is compounded by unclear review criteria that changes due to the iterative nature of data collection and screening.[6] While EPA has provided general inclusion criteria in Appendix G, of the NMP Problem Formulation, EPA has not provided information on how it applies these criteria to exclude relevant studies.

TSCA requires EPA conduct risk evaluations using the *weight of scientific evidence*. (TSCA §26(h)). As defined by EPA at 40 CFR 702.33, *weight of scientific evidence* requires, "a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses *a pre-established protocol* to *comprehensively, objectively, transparently, and consistently*, identify and evaluate each stream of evidence . . . " (italics added).

EPA's current systematic review process does not meet this standard. EPA's screening process for data is unclear and seems to change with each draft risk evaluation. The process is neither transparent nor consistent. ACA recognizes that EPA is still improving its systematic review process with each draft evaluation.

As part of its review of the draft 1-4 Dioxane risk evaluation, the Science Advisory Committee on Chemicals (SACC) recommended EPA not be overly stringent when applying criteria. ACA supports this recommendation and others by the SACC. ACA believes these recommendations will assist EPA in developing a systematic review process that meets the *weight of scientific evidence* standard. The SACC recommends:

- Documentation of how information was gathered and evaluated with detailed descriptions of the process;
- Transparency about how sources were identified and evaluated;

[6] EPA recognizes that application of review criteria is subject to change with each risk evaluation. As noted in the NMP Problem Formulation document, "Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the risk evaluation." (EPA, NMP Problem Formulation, Appendix G, p. 129).

- Following best practices in the field and simplifying data quality criteria;
- Not excluding studies on a single criteria or stringent application of criteria; and
- Submitting process for review of the National Academy of Sciences.

V. EPA Would Benefit from Continued Review of the Science Advisory Committee on Chemicals

The Science Advisory Committee on Chemicals (SACC) was established by EPA in 2016 under TSCA, 15 U.S.C. 2601 *et seq.,* as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 114-182, 140 Stat. 448 (2016), and operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix 2 (1972). Thus far, the SACC has provided detailed and useful preliminary evaluations of EPA's draft risk evaluations. The SACC performs a vital function of providing both EPA and the public its evaluation of the quality of EPA's draft risk assessments, in both written comments and extended review meetings, open to the public. At public meetings, SACC members question EPA representatives while also providing responses to issues identified by EPA.

The SACC has conducted such meetings for the first six draft risk evaluations covering: PV-29, HBCD, 1-4 Dioxane, 1-Bromopropane, Methylene Chloride, and NMP. Over the course of these six meetings, the SACC has developed guidance for EPA risk evaluations affecting consideration of PPE in risk evaluations, availability and quality of data, systematic review criteria, confidential business information (CBI) considerations for data and transparency, consideration of toxicological endpoints such as genotoxicity and other issues vital to the accuracy of TSCA risk evaluations. Further, at each meeting, the SACC, EPA and the public's understanding of these issues continues to evolve. In effect, by conducting public reviews of each draft risk evaluation, the SACC serves a vital function of establishing consistency and transparency in how EPA conducts risk evaluations.

At SACC's meeting to review the NMP draft risk evaluation, the SACC and EPA considered stopping SACC's review of each draft evaluation so it only convenes occasionally to discuss issues of emerging science that could affect how EPA conducts evaluations. ACA suggests that the SACC continue to conduct review of each draft risk evaluation at least through the next group of 20 TSCA risk evaluation chemicals. As EPA's process is unlikely to reach its zenith with completion of the first 10 reviews under TSCA, the SACC's continued review of each draft evaluation would maintain its valuable analysis of EPA's evolving process through each of the next 20 chemicals. In addition, based on the 9th Circuit's ruling in *Safer Chemicals Health Families, et. al. vs. EPA*, Case No. 17-72260, EPA may need to further adjust its approach to risk evaluations to consider aggregated effects and legacy uses. The SACC's continued input on these and other matters, through review of each draft risk evaluation, would assist EPA in establishing a consistent approach and applying it across risk evaluations. It also benefits the public providing insight and analysis in a public forum.

VI. Timing for Communication with SACC and Final Public Comment should be Extended Where Possible

ACA deeply appreciates EPA's extension of the final comment deadline from Jan. 6, 2020 to Jan. 21, 2020, especially considering both the Thanksgiving and Christmas Holiday periods that fell within the initial 60-day comment period. ACA suggests EPA consider similar extensions for future risk evaluations, even when not required by a holiday season, but rather due to the novelty of this process for stakeholders and the continued evolution of EPA's process.

With each draft risk evaluation, EPA evolves its approach to risk evaluation. Stakeholders appreciate extra time to review EPA's draft and comments by the SACC to develop meaningful and hopefully helpful comment to EPA.

The current tight public comment deadlines compromise stakeholder's ability to comment. With the NMP review, stakeholders had a mere 13 working days to submit comments to the SACC for it to consider comment prior to the SACC review meeting. EPA made the draft evaluation available online on Nov. 4, 2019, with official publication on Nov. 7, 2019. Stakeholders had to submit comments to the SACC by Nov. 21, 2019. SACC then held its meeting on Dec. 5-6. Stakeholders were then required to comment by Jan. 6, 2020, without the extension. This provided just 20 working days to comment after the SACC meeting (including the Christmas Holiday here as a working day, for the purpose of demonstrating typical time to comment). ACA appreciates that the total comment period is 60 days. The SACC review meeting however is helpful in analyzing aspects of the draft evaluation to assist in developing comment.

Additional time to comment would enhance quality of comments to EPA. ACA would suggest routinely extending the 60 day comment period to 90 days, at least during the evaluation process for the next round of 20 high priority chemicals finalized in December 2020 and for the remaining draft evaluations scheduled for publication in 2020. This extension is justified due to EPA's continued evolution of the risk evaluation process and would allow stakeholders to more deeply review and comment, while further considering the SACC's evaluation.

Such an extension is within EPA's discretion. EPA set the 60-day comment period by rule (40 CFR 702.49), but it is not a statutory requirement. EPA is required to complete evaluation within three to three and a half years from initiating evaluation. (15 U.S.C. §2605(4)(G)). ACA appreciates that EPA must operate under a tight schedule to complete a risk evaluation with this time frame, but would appreciate flexibility in providing comment. Similarly, ACA appreciates EPA's willingness to meet and communicate with stakeholders.

VII. Conclusion

ACA is concerned that EPA's risk evaluation of NMP will identify issues for further examination without clearly identifying conditions leading to unreasonable risk to workers and consumers. This in turn might result in EPA developing unnecessary or flawed risk mitigation measures. To improve the overall quality of the NMP risk evaluation and future risk evaluations, ACA suggests that:

- EPA gather additional data or provide further explanation related to identified issues in the final risk evaluation, particularly related to air concentrations and exposure times during formulation of products with NMP, application and use of relevant products for both consumers and workers and laboratory use;
- EPA recognize limitations of using the high end scenario during risk mitigation so as not prescribe unnecessarily restrictive and unjustified control measures, including banning NMP for uses relevant to paints, coatings, sealants and adhesives or setting unrealistic *de minimis* values;
- EPA require PPE where it has issued a finding of no unreasonable risk because PPE mitigates the risk;
- EPA publish a list of excluded studies with explanation of how it applied its hierarchy of controls and inclusion criteria;
- EPA adopt recommendations of the SACC related to improving systematic review, including detailed documentation and descriptions of data evaluation, transparency in the process, simplifying criteria and harmonizing criteria with best practices in the field, avoiding stringent application to exclude information and submitting to review of the National Academy of Sciences'
- EPA continue the current system of review by the SACC with a public meeting; and
- EPA routinely extend comment periods on draft risk evaluations by an additional 30 days — to 90 days — at least through the next round of 20 high priority chemicals.

EPA is charged with a formidable task and is committed to meeting the deadlines imposed by the *Lautenberg Act*. ACA appreciates the opportunity to work with EPA on these matters and will coordinate with the agency to assess how ACA can assist in improving data quality.

Please feel free to contact me as well about any of the issues identified herein.

Respectfully submitted,

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