Toxic Substances Control Act (TSCA) Risk Management Proposal for N-Methylpyrrolidone (NMP)

N-Methylpyrrolidone Producers Group (NMP Producers Group)
American Chemistry Council (ACC)

January 11, 2024

Agenda

- Risk evaluation (RE) and risk management must be based on best available science and weight of scientific evidence
- Reasonably available information should inform risk management proposal
- Risk management should regulate only to the extent necessary

Best Available Science and Weight of Scientific Evidence in TSCA Risk Evaluation

- Study selection for point of departure is not based on the best available science and weight of scientific evidence required by TSCA Section 26

- Blind panel of experts peer-reviewed available studies and concluded that the study selected by the U.S. Environmental Protection Agency (EPA) (Exxon 1991) does not reflect the best available science and weight of scientific evidence

  - Found that the Exxon 1991 study was "not a high-quality study" and "should not be considered for quantitative risk assessment"

- Results of panel review were published in peer-reviewed scientific journal in February 2023; Kirman *et al*. (2023)

Request for Correction (RFC) of Information in the RE Submitted in May 2023

- Kirman *et al*. (2023) was not published at the time of the RE and was submitted to EPA for consideration

- EPA's final RE includes questionable quality ratings for studies and does not address in the RE or the response to public comments in 2020 the data weaknesses outlined in the RFC

  - 2015 Work Plan Chemical Risk Assessment: EPA rated Sitarek and Stetkiewicz (2008) as "unreliable" due to inconsistencies in the published data. In the final RE, EPA rated this study as "high" quality without addressing the weaknesses
  - Exxon 1991 was rated "reliable with restrictions" in 2007 Organization for Economic Cooperation and Development (OECD) Screening Information Dataset (SIDS) review; two subsequent studies rated "reliable without restrictions"; in final RE, all three studies are rated as "high" quality
  - These arguments indicate flawed studies were used for point-of-departure designation, which ultimately led to additional conditions of use (COU) being incorrectly designated as presenting unreasonable risk

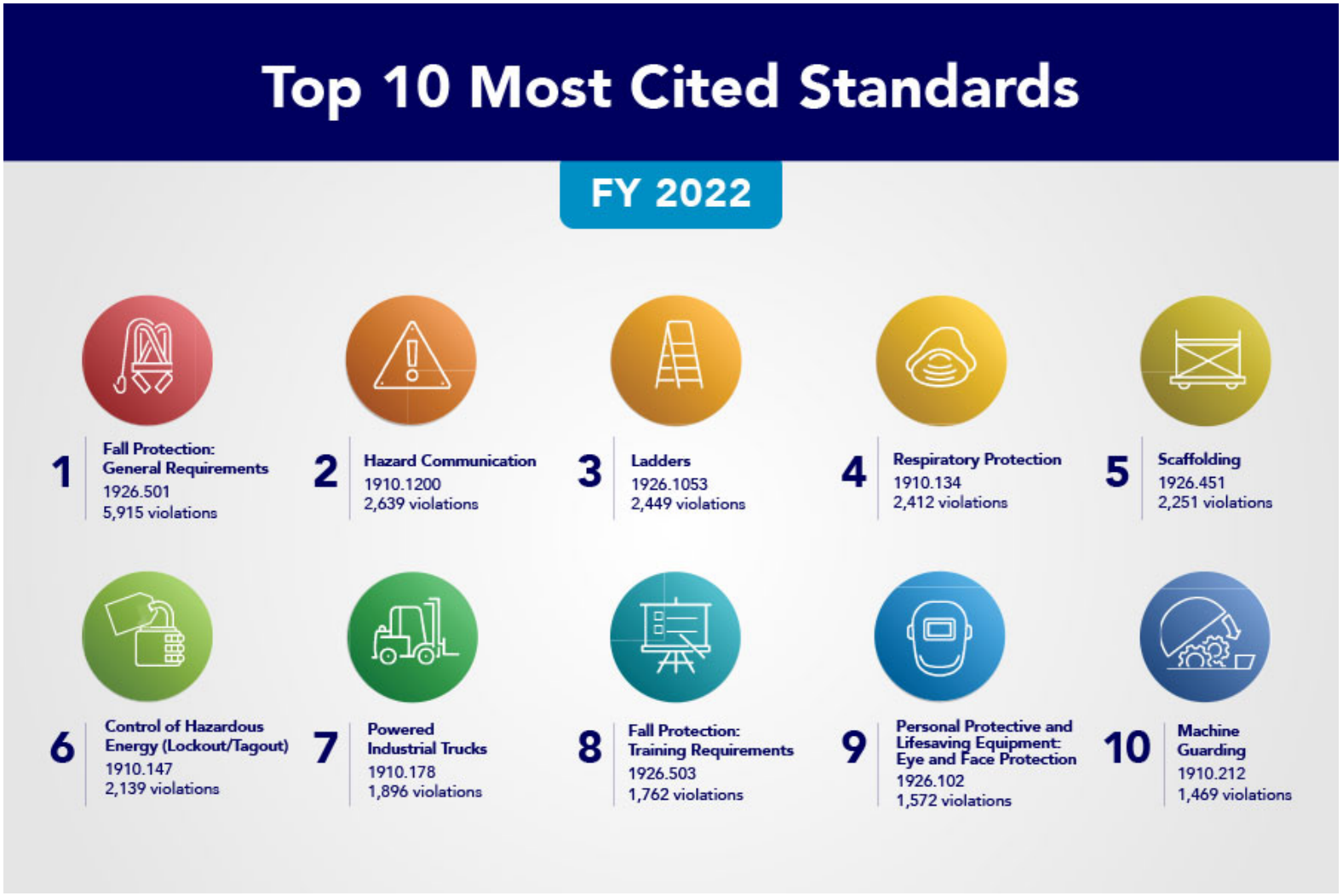
Request for Correction (RFC) of Information in the RE Submitted in May 2023

- The RFC was denied in August 2023
  - EPA stated in the response to the RFC that the issues were appropriately addressed during the RE public comment process
    - The denial language was duplicated from EPA's response to an RFC from a different group with different objections; shows less-than-thorough review
    - The RFC cited to 2019 Office of Management and Budget (OMB) memorandum to agencies. Agencies should provide RFC responses to OMB prior to issuing. NMP Producers Group is not aware if this occurred

Reasonably Available Information

- Assumption of no personal protective equipment (PPE) use is not supported by:
  - Stakeholder submissions -- engineering controls, work practices, PPE
  - Semiconductor Industry Association (SIA) data that were ignored (SIA's RFC also received perfunctory denial)
  - Occupational Safety and Health Administration (OSHA) enforcement statistics
    - EPA cites to OSHA's "Top 10 Most Frequently Cited Standards" as evidence that PPE non-use is reasonably foreseen
    - https://www.osha.gov/top10citedstandards

Reasonably Available Information



Reasonably Available Information

- Only two of the 10 most cited violations relate to the chemical industry -- hazard communication and respiratory protection violations. The eye protection violations relate to construction standards, not general industry standards that would apply to the chemical industry
- Searching on North American Industry Classification System (NAICS) 325 (chemical manufacturing) shows violations of glove and eye protection requirements are each less than 1 percent of all violations
- Source: https://www.osha.gov/ords/imis/citedstandard.naics?p_esize=&p_state=FEFederal&p_naics=325
  - EPA assumes that PPE are not always provided and not required to be used, meaning, in practice, that EPA assumes that PPE are never provided and never required to be used
  - Data show otherwise

- If Congress intended for EPA to make worst-case assumptions even when data show otherwise, Congress would not have required EPA to use "reasonably available information."

Consider Downstream Impact If Industrial Use Is Prohibited

- **NMP is used by industry in production of other materials** (*i.e.*, polymers, resins, articles)
- Prohibiting these uses will have **impact to downstream users** (in some applications there is no simple replacement solvent available)
- Examples:
  - NMP used as **polymerization solvent** to make Kevlar® para-aramid polymer
    - Kevlar® has many applications including in aerospace, defense (body armor, military helmets/shields, military vehicles), personal protective equipment (gloves/sleeves, firefighter and military apparel), automotive (tires, brakes, hoses)
  - NMP used as **cleaning solvent** in operation that makes parts for semiconductor manufacturing
- Suggest **restriction (WCPP) in industrial uses** with a ***de minimis*** **value** as NMP could be present in downstream materials or present as impurity in raw materials that would also carry forward into finished products

FORTRON® POLYPHENYLENE SULFIDE (PPS)

- Fortron Industries LLC, Small Business JV operated by Celanese in Wilmington, NC
- Product Properties: High temperature stability, High Chemical resistance, Inherent flame resistance, High stiffness and strength, lightweight
- End-use products include automotive, aerospace, electronics, energy
- Outside of the U.S. these products can only be sourced from Asia (supply chain impacts/no alternatives)
- Exposure controls for employees
- PPS product poses no consumer risk

Celanese

NMP Uses Are Diverse

- NMP was developed in the early 1900s to replace more toxic solvents, such as chlorinated solvents and benzene

- Has beneficial properties for chemical processing, as well as transport, storage, and handling:

  - High boiling point, low freezing point, low volatility, high flash point/low flammability
  - Low viscosity, non-corrosive to metals
  - Chemically and thermally stable; does not interfere with reactions
  - Functions well in aqueous, organic, and inorganic media
  - One of very few polar, aprotic (not acidic or basic) solvents

- For these reasons, it is useful in many industrial processes such as pharmaceuticals, semiconductor/lithium ion batteries, general chemical/polymer processing, automotive, extractions, and purifications

- End uses are broad and vast and have many downstream effects if industrial uses are not allowed to continue

Regulating Only to the Extent Necessary

- TSCA requires that EPA regulate to the extent necessary to address unreasonable risks
- Workplace chemical protection programs (WCPP) that reduce "unreasonable risk" to "no unreasonable risk" meet the "extent necessary" standard
- Workplaces that can demonstrate compliance with WCPP should be allowed to continue
- COUs should only be prohibited in workplaces that cannot meet a WCPP (including an existing chemical exposure limit (ECEL)) and do not qualify for a crucial use exemption
- It would make no sense that TSCA Section 6(a) authorizes EPA to address activities that do not contribute to or are not necessary to mitigate an unreasonable risk
- Outright prohibitions are overregulation and unnecessary if WCPP (including, as appropriate, an ECEL) can be met
  - If EPA must ban everything that is hazardous unless there is a critical use, EPA will ban nearly everything

Regulating Only to the Extent Necessary

- Exemptions are necessary, especially for essential/critical uses
- Many end uses and end users rely on products that are made with or using NMP
  - Semiconductors
  - Nylon products (Kevlar, automotive)
  - Gas separation
- *De minimis* concentration must be established
  - The European Chemicals Agency (ECHA) established a threshold of 0.3% for its restriction of NMP in a mixture (intentional or not)
- If EPA plans on taking a TSCA Section 6(g) approach -- only allowing certain COUs going forward -- EPA must review carefully the myriad specific uses that are covered by a broader COU (*e.g.*, solvent or processing aid)
  - Some stakeholders that use NMP as a solvent or processing aid may not have commented
  - Downstream stakeholders of products made from NMP may not be aware that NMP is critical in their supply chains

Thank You