American Chemistry Council | Chlorine Panel

TSCA RISK MANGEMENT RULE

OMB MEETING METHYLENE CHLORIDE

February 29, 2024

OVERVIEW

01
Scientific Concerns

02
Compliance and Implementation Issues

03
Economic Impacts

04
Recommendations

05
TSCA Process Concerns

American Chemistry Council | Chlorine Panel

THE SCIENCE IS FLAWED

Questionable Scientific Foundation

EPA's proposed exposure limits (ECEL and STEL) are misaligned with the bulk of scientific evidence, overlooking inputs from NAC-AEGL and EPA’s own SACC.

Data Interpretation Issues

Challenges with EPA's use of acute and chronic toxicity data, especially regarding central nervous system effects and liver vacuolation. EPA’s analysis ignores key epidemiological evidence and alternative, yet valid, scientific views.

Methodological Concerns

EPA's dismissal of PBPK modeling for exposure estimation, favoring less accurate methods contrary to scientifically robust approaches.

American Chemistry Council | Chlorine Panel

Cross-Cutting ECEL Concerns

EPA should clarify when exceedance of the ECEL represents non-compliance. Compliance should be based on:

(1) At least six personal breathing zone monitoring samples, consistent with guidance from the American Industrial Hygiene Association, with

- A “rolling average” calculated with these recent measurements;

(2) Incorporation of task-based measurements that permit the inclusion of Assigned Protection Factors (APFs) when assessing exposure for short-terms tasks, as per current methods

- Use the APF for PPE to determine compliance against the EPA ECEL or STEL; and

(3) The 'control-banding-by-task' approach, allowing for a more targeted evaluation of task-specific scenarios within well-defined Similar Exposure Groups, rather than relying solely on full 8-hour data.

If the ECEL is implemented as an occupational exposure limit, instead of assuming exposure for total work hours, the final rule should allow the ECEL to be refined using the time spent completing tasks with potential exposure.

ESTABLISHMENT OF A *DE MINIMIS* EXCLUSION IS ESSENTIAL

Issue: The current absence of a *de minimis* exemption for methylene chloride content in products. EPA has proposed a *de minimis* limit for PCE but not for any other solvents.

Consequences:

- Potential widespread non-compliance.
- Unnecessary penalization of minor, non-risk-contributing uses of methylene chloride.

Proposal: EPA should set a *de minimis* level across the board to support regulatory harmonization and compliance certainty.

Benefits:

- Reduces the burden on businesses while maintaining health and safety standards.
- Encourages compliance by acknowledging practical usage contexts.

American Chemistry Council | Chlorine Panel

ECONOMIC IMPACT AND ALTERNATIVES

- Economic impact on small businesses not fully considered, especially on commercial furniture refinishing.
- Questionable availability of safer, effective alternatives.
- EPA's analysis may not fully comply with TSCA Section 6(c).

American Chemistry Council | Chlorine Panel

METHYLENE CHLORIDE USED IN CLOSED LOOP PROCESSES

Particularly used in heat transfer processes to minimize environmental exposure and enhance worker safety.

American Chemistry Council | Chlorine Panel

REQUEST FOR EXTENDED COMPLIANCE TIMELINES

To ensure an orderly transition and compliance with the proposed rule, extended timelines are essential. EPA should allow **3-5 years** after publication of the final rule for full implementation of the Workplace Chemical Protection Programs (WCPP).

Areas Needing Extension:

- Initial monitoring phases.
- Development of WCPP.
- Adoption of engineering and administrative controls.

Rationale: Longer periods are essential for industry to:

- Adequately prepare and implement safety measures.
- Ensure thorough training and awareness for staff.
- Integrate new protocols without disrupting operations.

TSCA PROCESS CONCERNS

EPA's Prohibition on Industrial Uses

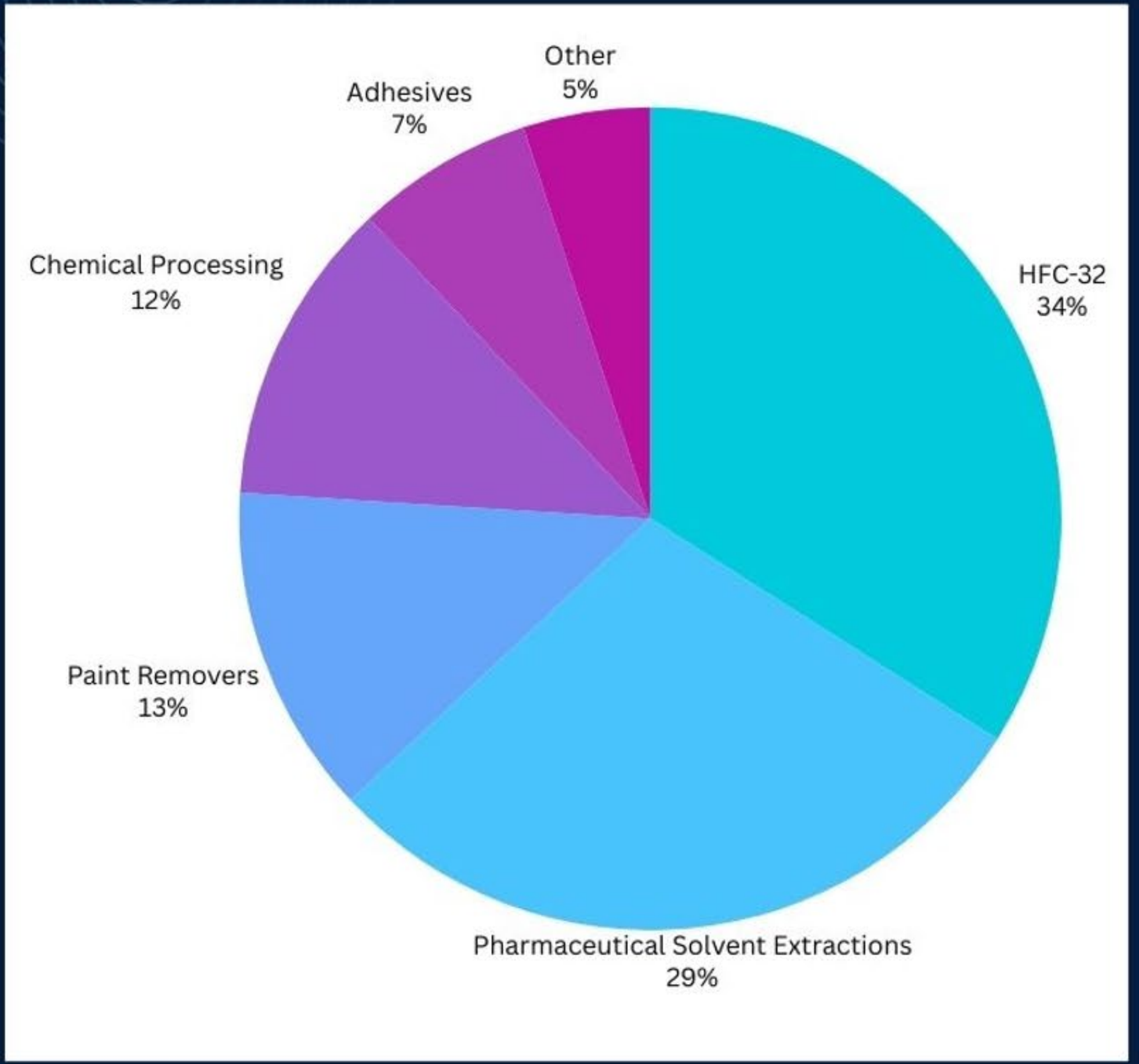
- EPA proposes to prohibit 32 of 43 industrial and commercial applications based on concerns about feasibility of implementing an ECEL.
- **Recommendation:** Instead of prohibitions, EPA should establish an ECEL, allowing industries to demonstrate compliance through a WCPP with a reasonable compliance period.

Incorporating Workplace Safety Measures

- EPA's "no PPE" policy overlooks existing OSHA workplace safety standards.
- **Recommendation:** The final Risk Management Rule should integrate existing OSHA-mandated safety measures, including PPE, industrial hygiene practices, and standard operating procedures, into the WCPP framework.

Methylene Chloride U.S. Consumption in 2020

- **75%** of specific industries rely on closed-loop processing system.
  - Pharmaceuticals
  - HFC-32 production
  - Chemical processing



Source: Chemical Economics Handbook, 2021

American® Chemistry Council | Chlorine Panel

Thank you