



# The Final Methylene Chloride Risk Management Rule - Lessons Learned By Industry

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# Herb Estreicher, Ph.D.

- ◆ Herb Estreicher is a prominent environmental lawyer who holds a Ph.D. in Chemistry from Harvard University in addition to his U.S. law degree. Herb is an expert on the TSCA and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He has successfully argued many cases before the European Chemicals Agency Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.
- ◆ Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.
- ◆ Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe and advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directive.



# Gregory A. Clark

- ◆ Gregory (Greg) Clark counsels clients on regulatory and environmental issues, focusing on the Toxic Substances Control Act (TSCA), the Clean Air Act (CAA), state volatile organic compound (VOC) regulations, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA).
- ◆ He assists clients needing approval of new chemical substances, genetically modified organisms (GMOs), and pesticides under TSCA, FIFRA, and similar laws abroad. Clients value his extensive experience guiding them through the PMN, Low Volume Exemption, Microbial Commercial Activity Notice (MCAN), and TSCA Environmental Release Application (TERA) review processes.
- ◆ Greg's extensive background enables him to provide guidance to companies and trade associations on the prioritization, risk evaluation, and risk management of existing chemicals, including chemicals on the 2014 TSCA Work Plan, following the Lautenberg Act amendments to TSCA. He assists companies with periodic reporting under the TSCA Chemical Data Reporting Rule and other agency reporting programs. He also designs, conducts, and coordinates comprehensive internal audits of TSCA compliance for existing operations under EPA's "Audit Policy," as well as under other penalty mitigation policies.





# David B. Fischer

- ◆ David Fischer counsels clients on environmental, policy, and health and safety matters, with a concentration on the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Having served as the Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention as well as having held senior level positions at the American Chemistry Council, David advocates for clients before the U.S. EPA and provides strategic advice to them regarding issues before Congress.
- ◆ In addition, he has experience with numerous other statutes including the CAA, CWA, Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Safe Drinking Water Act (SDWA), Emergency Planning and Community Right-to-Know Act (EPCRA), and the Food Quality Protection Act (FQPA).
- ◆ David's clients include domestic and international industrial and specialty chemical manufacturers and the trade associations that represent them. Clients seek his assistance on new chemical approvals, chemical and pesticide risk evaluations, and risk management rulemaking because of his deep understanding of EPA, its internal science policy apparatus, and its many organizational pieces, responsible for all aspects of TSCA and FIFRA.



# Opportunities for Industry Engagement— Risk Management Phase

- ◆ Required Consultations with different governmental entities. Some consultations are open to the public.
- ◆ Public Meetings and Webinars.
- ◆ One-on-One Meetings.
- ◆ Public Comment period on proposed Risk Management rule.
- ◆ Possibility of post-comment period meetings with stakeholders.

# Summary of the Final Rule

- ◆ For a handful of highly industrialized uses, EPA has created a Workplace Chemical Protection Program (WCCP) with strict exposure limits (ECEL = 2 ppm TWA), monitoring requirements, and worker training and notification requirements.
- ◆ Uses that will continue under the WCCP were those where EPA received data and other information showing workplace safety measures could address the unreasonable risk. These uses include:
  1. **Use in the production of other chemicals, including refrigerant chemicals.**
  2. **Production of battery separators for electric vehicles.**
  3. **Use as a processing aid in a closed system.**
  4. **Use as a laboratory chemical.**
  5. **Use in plastic and rubber manufacturing, including polycarbonate production.**
  6. **Use as a bonding agent in solvent welding.**
- ◆ Additionally, specific uses of MC required by NASA, DOD, and FAA were granted 6(g) exemptions.
- ◆ EPA also established a 0.1% a de minimis concentration where WCCP is not required.

# Proposed Rule (88 FR 28284 May 2023)

- ◆ EPA proposed bans but also suggested WCCP as an alternative regulatory measure for the above-bolded uses.
- ◆ EPA stated its belief that a WCCP had the potential to be a viable alternative to the proposed bans.
- ◆ However, at the time of proposal, EPA did not have reasonably available information that could confirm that compliance with an ECEL of 2 ppm was possible (e.g., monitoring data or detailed description of activities involving MC for these conditions of use).
- ◆ Therefore, EPA preliminarily proposed that these conditions of use be banned.



# Comments by Industry Saved Uses from Being Banned

- ◆ 40 Industry comments on specific uses.
- ◆ Most comments involved use of MC as a processing aid.
- ◆ Some commenters provided detailed information showing that exposures are carefully controlled.
- ◆ Some commenters provided monitoring data demonstrating that they could meet the ECEL.
- ◆ After the close of the public comment period, EPA held meetings with stakeholders to receive clarifying information related to the use of MC.
- ◆ Topics of these meetings included exposure controls, process descriptions, monitoring data, and specific conditions of use.
- ◆ EPA received data as part of and following these stakeholder meetings.

# What Happened to 6(g) Exemption Requests

- ◆ Most unnecessary as WCCP compliance was substituted for bans.
- ◆ For example, EPA proposed a 10-year time-limited 6(g) exemption for the use of MC in battery separator manufacturing but this was no longer needed because WCCP allowed.
- ◆ Proposed rule included an analysis for a 6(g) exemption for industrial and commercial use of MC as a paint and coating remover in furniture refinishing.
- ◆ Broad exemption not warranted but extended phase-out period allowed for removing coatings from wooden furniture and other items that are of artistic, historic or cultural significance.

# Elements and Deadlines for WCPP

- ◆ Initial monitoring: 360 days (*was 180 days*)
- ◆ Periodic monitoring: as early as every 3 months after initial
- ◆ No exposure > ECEL or STEL: 450 days
- ◆ Establish regulated areas: 450 days (*~270 days*)
- ◆ Respiratory protection: 450 days (*270 days*)
- ◆ Dermal protection: 450 days
- ◆ Hierarchy of controls: 540 days (*360 days*)
- ◆ Exposure control plan: 540 days (*360 days*)
- ◆ Notification of monitoring results

# Key Uses Subject to Ban or Phaseout, not WCPP

- ◆ Refinishing of wooden pieces that are of artistic, cultural or historic value (subject to 5-year phaseout)
  - ◇ Specific exposure controls required during the phaseout
- ◆ Industrial and commercial use in finishing products for fabric, textiles, and leather
- ◆ Electrical equipment, appliance, and component manufacturing
- ◆ Cellulose triacetate film production
- ◆ Industrial and commercial use for oil and gas drilling, extraction, and support activities



# Other Notable Approaches and Denials

- ◆ EPA default remains a ban, absent evidence of ability to comply with the ECEL and STEL
- ◆ 2 ppm ECEL and 16 ppm STEL were not changed despite robust scientific evidence from commenters
- ◆ *De minimis* exemption only applies to “products”
- ◆ EPA extended deadlines for steps in the WCPP but not to the full extent requested
- ◆ Viability of comments other than the primary alternative regulatory action?

# Observations and Cautionary Notes

- ◆ It was feasible for many occupational COUs to meet the ECEL of 2 ppm relative to the current PEL of 25 ppm.
- ◆ For other solvents undergoing risk management rulemaking, the disparity between the ECEL and PEL spans orders of magnitude (e.g., TCE).
- ◆ But as noted, providing data to EPA is critical.
  - ◇ EPA receptive to industry input on technical and feasibility arguments, but much less so with regard to scientific arguments.
  - ◇ 6(g) exemptions should be requested *before* EPA issues a proposed rule.

# Observations and Cautionary Notes

- ◆ EPA states that its overall goal of risk management is to identify controls that are permanent, feasible, and effective.
- ◆ In the formaldehyde risk evaluation, EPA explicitly states that the “occupational exposure value” calculated at 10 ppb and based only on risk factors will not be the same as the ECEL in any proposed risk management rule.
  - ◆ Query whether TSCA allows that?



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# Thank You

Any questions?



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