



WASHINGTON WATCH

Chemical Restrictions and TSCA's Growing Commercial Influence

By Lynn L. Bergeson

This past spring, the United States Environmental Protection Agency (EPA) issued a first-ever final rule under Section 6(a) of the Toxic Substances Control Act (TSCA) banning the use of methylene chloride in consumer paint and coating removal products. Although this rule was long in the making, this type of chemical ban of selected products is likely to be seen more routinely in the months and years ahead. This article reflects upon EPA's broad authority under TSCA Section 6 and explores the reasons why chemical prohibitions, and the commercial complications they inspire, are expected to be the new normal.

New TSCA and Section 6

You might be wondering why this topic is emerging now, as TSCA Section 6(a) has for decades authorized EPA to regulate, even ban, the use of a chemical substance if the Agency determines that the use at issue causes unreasonable risk to human health or the environment. The answer is that in 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) significantly revised TSCA Section 6, and EPA is now implementing that authority. Lautenberg added prioritization and risk evaluation steps to the process, deleted the problematic "least burdensome requirement," the implementation of which has plagued EPA for decades, and mandated aggressive timelines for completion of the key steps in the risk evaluation process, the results of which we are seeing in real time now.

The new chemical prioritization process under Lautenberg establishes a mandatory risk-based screening process, including criteria for designating high-priority and low-priority chemicals for the risk evaluation step. This process effectively requires EPA to prioritize for evaluation *all* chemicals in

commerce deemed “active” and to place them in a high-priority or low-priority bucket. All chemicals in the high-priority bucket will be evaluated for risk; all risks, under this process, must be regulated to eliminate the risk. EPA is required to designate as high priority chemicals that the Agency “determines, without consideration of costs or other nonrisk factors, may present an unreasonable risk ... because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant” (EPA, 2019a, p. 10492) by EPA. Chemicals that do not meet this standard are designated as low-priority substances.

EPA was required under Lautenberg to initiate risk evaluations for ten chemicals fairly immediately after Lautenberg’s enactment and to identify 20 high- and 20 low-priority substances by the end of this year. EPA identified the ten chemicals for risk evaluation in a timely manner and has released over the past year four of the ten required risk evaluations that it must complete by the end of 2019 (with the possibility of a brief extension into 2020). These risk evaluations have been (or will be) conducted under provisions derivative of Lautenberg. For chemical substances listed in EPA’s 2014 update to the TSCA Work Plan for Chemical Assessments that EPA completed a risk assessment *prior to* Lautenberg’s enactment, TSCA Section 26(l)(4) provides that EPA “may publish proposed and final rules under [TSCA Section 6(a)] that are consistent with the scope of the completed risk assessment and consistent with other applicable requirements of [TSCA Section 6]” (U.S. EPA, 2018, p. 93). Methylene chloride is such a chemical substance, and the final rule issued this spring reflects a risk evaluation that pre-dates Lautenberg. Whether EPA’s risk evaluation was completed before Lautenberg’s enactment, as is the case for methylene chloride, or post-dates Lautenberg’s enactment, as is the case for the ten risk evaluations now underway as well as those that will be completed in the years to come, the result is the same -- chemical uses deemed to pose an unreasonable risk will be regulated to eliminate the risk or banned if the risk cannot be abated. It is this bottom line that chemical stakeholders need to understand, as EPA’s actions under TSCA Section 6 are expected to pick up in speed and intensity.

Methylene chloride final rule

To appreciate the magnitude of the potential commercial implications of the TSCA risk evaluation process, it is helpful to review in detail the methylene chloride final rule. EPA proposed under TSCA Section 6(a) risk management restrictions on methylene chloride and N-methylpyrrolidone (NMP) in January 2017 (U.S. EPA, 2017). EPA proposed, among other restrictions, to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for consumer and most types of commercial paint and coating removal. EPA also proposed similar restrictions for NMP, along with alternative proposals. In the final methylene chloride rule, EPA decided not to issue a final regulation regarding NMP as part of its action. Instead, the Agency indicated that it intends to incorporate NMP use in paint and coating removal products into the risk evaluation it is currently conducting under TSCA Section 6(b).

The final rule issued on March 27, 2019, (U.S. EPA, 2019b) prohibits the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal for all consumer uses and prohibits the distribution in commerce of methylene chloride in paint and coating removal products intended for consumer use and distribution to and by retailers (U.S. EPA, 2019b). A retailer is defined as any person or business entity that distributes or makes available paint and coating removal products to consumers, including through e-commerce Internet sales or distribution. If a person or business entity distributes or makes available any methylene chloride-containing paint or coating removal product to at least one consumer, then it is considered a retailer. For a distributor not to be considered a retailer, it must distribute or make available methylene chloride-containing paint and coating removal products solely to commercial or industrial end users or businesses.

The rule requires manufacturers, processors, and distributors of methylene chloride for any use, excluding retailers, to provide downstream notification of the prohibitions in this final rule through safety data sheets (SDS) by adding to Sections 1(c) and 15 of the SDS the following language: "This chemical/product is not and cannot be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for consumer paint or coating removal" (U.S. EPA, 2019b, p. 11429). According

to EPA, downstream notification “ensures that processors and distributors are aware of the restrictions for methylene chloride in paint and coating removal; enhances the likelihood that the risks associated with this use of methylene chloride are addressed throughout the supply chain; and also streamlines compliance and enhances enforcement, since compliance is improved when rules are clearly and simply communicated” (U.S. EPA, 2019b, p. 11429). The rule also requires recordkeeping relevant to these prohibitions.

The prohibition on manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal, including distribution to and by retailers, will take effect six months after the effective date of the final rule, or on November 22, 2019. EPA states that it “believes this is a reasonable transition period and will not result in additional costs of collecting and disposal of any stranded products” (U.S. EPA, 2019b, p 11429). EPA acknowledges that some individual retailers might not be as efficient with their inventory management, resulting in stranded products and some additional costs for disposal of such products.

After August 26, 2019, each person who manufactures, processes, or distributes in commerce methylene chloride must retain documentation of the entities to which methylene chloride was shipped, a copy of the downstream notification provided, and the amount of methylene chloride shipped. The documentation must be retained for three years from the date of shipment. The final rule also includes a definition of retailers and consumer paint and coating removal to be responsive to comments received requesting that EPA provide more clarity regarding the regulated distribution to consumers.

TSCA Section 6(a) requires EPA to impose one or more of the specified requirements “to the extent necessary” so that a chemical substance no longer presents an unreasonable risk identified by EPA. In the case of methylene chloride, EPA determined that the downstream notification provisions are necessary to prevent the identified unreasonable risk. EPA states that without downstream notification, manufacturers, processors, and distributors are likely to be unfamiliar with the prohibitions against distribution of methylene chloride-containing paint and coating removal products to and by retailers. As such, the notification helps ensure that all

downstream entities are aware of the prohibitions. Notification throughout the supply chain also streamlines compliance and enhances enforcement, since, according to EPA, compliance can be improved when rules are clearly and simply conveyed.

Persons who import any chemical substance governed by a final TSCA Section 6 rule are subject to TSCA Section 13 import certification requirements and the corresponding customs regulations.¹ To comply with the import certification requirements, importers (or their agents) will be required to certify that the shipment of methylene chloride complies with all applicable rules and orders under TSCA. Any entity that exports or intends to export methylene chloride is subject to the export notification provisions of TSCA Section 12(b) and must comply with the export notification requirements.²

Significant penalties apply in cases of noncompliance. TSCA Section 15 makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA Section 6. Any failure to comply with the final rule when it becomes effective would be a violation of TSCA Section 15. Section 15 makes it unlawful for any person to fail or refuse to establish and maintain records as required by the rule; fail or refuse to permit access to or copying of records, as required by TSCA; or fail or refuse to permit entry or inspection as required by TSCA Section 11. EPA notes that violators may be subject to both civil and criminal liability. Under the penalty provision of TSCA Section 16, any person who violates Section 15 could be subject to a civil penalty for each violation. Each day in violation of this final rule, after the effective date, could constitute a separate violation. Knowing or willful violations could lead to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies are available to EPA under TSCA.

EPA states that individuals, as well as corporations, could be subject to enforcement actions. TSCA Sections 15 and 16 apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

As restrictive as the final rule is, it did not go far enough, according to some. On April 18, 2019, a coalition of groups representing worker rights organizations sued EPA in the U.S. Court of Appeals for the Second Circuit claiming that the final rule leaves workers unprotected and at risk. (Labor Council for Latin American Advancement & EPA, 2019). The case is pending.

Training, certification, and limited access for methylene chloride

On the same day it issued the final rule, EPA issued an advance notice of proposed rulemaking (ANPR) to obtain information on training, certification, and limited access options to address unreasonable risks that EPA could find with respect to methylene chloride when used for commercial paint and coating removal products (U.S. EPA, 2019c). EPA issues ANPRs to signal its preliminary thoughts on a particular topic, to generate public comment, and to invite input. The ANPR reflects considerable creativity and commercial sophistication on EPA's part, and stakeholders are urged to review the notice.

One approach that the EPA is considering in the ANPR is a regulation that could limit access to methylene chloride for commercial paint and coating removal by only allowing use by those individuals who have certified that they are able to engage in safe work practices such that any unreasonable risk is not present. EPA acknowledges that other, more restrictive, regulatory approaches may be appropriate for some conditions of use of methylene chloride for which EPA determines that unreasonable risk is present. EPA states that several considerations related to commercial uses of methylene chloride for paint and coating removal suggest that regulations allowing for limited access to the chemical, rather than a full prohibition on distribution for all commercial paint and coating removal, could be effective at addressing any unreasonable risks that EPA could potentially find to be present, while allowing continued use. For example, workplaces that have robust environmental, safety, and health protection programs and are in compliance with the Occupational Safety and Health Administration's (OSHA) methylene chloride standard (which contains requirements for the use of engineering controls, personal protective equipment (PPE), training, and other requirements to protect employees from methylene chloride exposure) are likely to address any risks that the Agency could potentially find to be present from exposure to methylene chloride during commercial paint and

coating removal so that they are no longer unreasonable. EPA notes that because more than 90% of methylene chloride manufactured (including imported) in the United States is estimated to be used for purposes other than paint and coating removal, employers and employees in those sectors may have considerable experience in work practices or other controls that could be transferred to paint and coating removal processes (U.S. EPA, 2019c).

The ANPR discusses numerous examples that could serve as models for a training, certification, and limited-access regulatory scheme. These examples include restricted-use pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), refrigerant certification under the Clean Air Act (CAA), the Lead Renovation, Repair and Painting, and Abatement Program, the Asbestos Certification Program, the methylene chloride certification program implemented in the United Kingdom as a derogation from the restrictions on commercial use in paint and coatings removal under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in the European Union, and others. Some of the examples encompass all of the elements of training, certification, and limited access, whereas others are more limited in their scope (U.S. EPA, 2019c).

In the ANPR, EPA states that training for safe work practices could be part of the requirements needed to obtain a certification of ability to engage in safe work practices for commercial paint and coating removal with methylene chloride. The training required could include training on how to handle, use, and dispose of methylene chloride for paint and coating removal so that any unreasonable risks that EPA could potentially find to be present are not present; proper use of engineering controls and PPE; accident prevention; emergency response; preparing and maintaining proper records; the hazards associated with use of methylene chloride for paint and coating removal; the route(s) of worker exposure; methods of detecting the presence of methylene chloride; symptoms of overexposure; medical treatment for overexposure; and explanation of SDSs and labeling requirements. EPA could also require that the training be tailored to describe measures that address specific exposure scenarios for methylene chloride for paint and coating removal, such as those scenarios that have resulted in fatalities (U.S. EPA, 2019c).

EPA states that the certification component of the program could mandate that commercial users be certified as able to engage in safe work practices with methylene chloride for paint and coating removal. Certification could provide documentation to EPA, distributors, and, potentially, interested members of the public that an individual is able to engage in safe work practices with methylene chloride for commercial paint and coating removal. To the extent that knowledge of other pertinent federal or state requirements (e.g., OSHA's occupational health standard for methylene chloride) is considered an integral component of the ability to engage in safe work practices, attesting to such knowledge may be a prerequisite to or a part of obtaining certification (U.S. EPA, 2019c).

The limiting access component of the program could limit the sale of methylene chloride for paint and coating removal. This component could allow for continued access and use of methylene chloride for specific paint and coating removal uses by certified commercial users or trained individuals while preventing access to methylene chloride-containing paint and coating removers by noncertified commercial users.

Discussion

The detailed overview of the final rule, and the scope of the ANPR, should leave no doubt as to EPA's broad authority under TSCA Section 6. The entire value chain, from chemical manufacturers and importers to downstream paint and coatings formulators and distributors, is affected by the final rule, resulting in considerable commercial disruption and potentially significant enforcement consequences in the event of noncompliance.

The final rule does not take action to regulate commercial use of methylene chloride as a remover for paints and coatings. Instead, EPA solicited comment on questions related to a potential training, certification, and limited-access program as an option for risk management for this commercial use of methylene chloride. While some observers claimed that EPA's decision not to regulate commercial uses at this time is due to industry bias, others viewed the decision as a proper exercise of EPA's due diligence in fully considering the "primary alternative regulatory actions" required under TSCA. EPA has appropriately identified existing regulatory models that could potentially be useful in one or more of the aspects involved in

establishing a training, certification, and limited-access program regulating commercial use of methylene chloride paint and coating removers. Appropriate care and due diligence in considering regulatory options were two of the important changes in TSCA Section 6(c) to address the issues presented by the *Corrosion Proof* decision regarding “least burdensome” in old TSCA while ensuring that EPA thinks carefully about its chosen regulatory approach and why it was preferred above others.

TSCA’s reach and considerable market influence under Section 6 is just beginning to be felt, with methylene chloride and specific consumer uses first out of the block. Interestingly, even *before* regulatory measures were implemented, some retailers opted to undertake voluntarily measures in response to the concerns expressed about methylene chloride in certain use patterns. Lowe’s, a major retailer, elected to stop stocking consumer products containing methylene chloride for paint and coating removal well before EPA mandated this result (Lively, 2018).³ This decision was directly related to EPA’s and other regulatory bodies’ review of this consumer use of methylene chloride and the potential risks these applications were thought to pose. The decision, although somewhat controversial, was not entirely unexpected, and chemical manufacturers and product formulators, particularly of products destined for consumer markets, can expect retailers to listen carefully to their customers and take actions believed to align with their wishes regardless of what EPA may ultimately decide to do. With respect to methylene chloride, EPA ultimately determined to ban consumer products containing methylene chloride for paint and coating removal. Arguably, if EPA had decided on a less drastic regulatory measure, the decision of Lowe’s would not necessarily have been any different. Whether such corporate decisions undermine EPA’s influence and/or the underlying goals of TSCA reform is unclear, but this issue remains a hotly debated topic.

The four ongoing risk evaluations noted earlier may well invite a new round of risk mitigation measures for any conditions of use deemed to pose unreasonable risks. It is not a stretch to anticipate voluntary product withdrawals or other commercial responses to draft risk evaluations, depending on their preliminary findings. For example, the draft risk evaluation issued on August 9, 2019, for 1-bromopropane (1-BP) states that there could be unreasonable risks to workers, occupational non-users,

consumers, and bystanders under certain conditions of use. It could be a while before EPA takes any final action, and stakeholders may decide voluntarily to take steps now to limit the marketability of the product based entirely on these draft risk findings.

All such decisions, mandated or voluntary, and their market effects, will soon become the new normal, and chemical stakeholders need to adjust accordingly. Chemical stakeholders should carefully monitor EPA's TSCA chemical risk evaluation process. Stakeholders need to know which chemicals are listed on the 2014 Work Plan for Chemical Assessments and the identity of the additional 20 high-priority chemicals that EPA is slated to announce in final later this year (a proposed list was identified in March 2019; see U.S. EPA [2019a]). As illustrated in the methylene chloride final rule, the EPA broad authority to regulate, including banning, a chemical substance in uses determined to pose unreasonable risk. Whatever the control measures EPA may ultimately decide to impose on any chemical substance, it will have significant commercial implications for the entire value chain. As demonstrated earlier, the market reacted even before EPA took final action, and retailers and others can be expected increasingly to self-select regulatory measures believed to align with corporate policies and commitments to customers and other stakeholders.

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End Notes

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- ¹ 19 C.F.R. §§ 12.118 through 12.127; *see also* 19 C.F.R. § 127.28.
 - ² 40 C.F.R. Part 707, Subpart D.
 - ³ In May 2018, Lowe's announced that it would phase out paint removal products containing methylene chloride by the end of 2018. The decision of Lowe's was reportedly based on its commitment to provide safer, affordable options to its customers.