Wednesday, March 20, 2019

On March 15, 2019, the U.S. Environmental Protection Agency (EPA) published a signed final rule that prohibits the manufacture (including import), processing, and distribution of methylene chloride for consumer paint and coating removal. EPA states that it “determined that the use of methylene chloride in consumer paint and coating removal presents an unreasonable risk of injury to health due to acute human lethality.” Under the final rule, paint removal products containing methylene chloride will not be able to be sold at any retail or distribution establishments that have consumer sales, including e-commerce sales. The final rule also requires manufacturers, processors, and distributors to notify retailers and others in their supply chains of the prohibitions and to keep records. The final rule will be effective 60 days after publication in the Federal Register, and the prohibitions will begin 180 days after the effective date of the final rule, providing time for establishments selling this chemical to consumers to come into compliance with the ban. Additionally, EPA is soliciting public input for a future rulemaking that could establish a training, certification, and limited access program as an option for risk management for all of the commercial uses of methylene chloride in paint and coating removal. EPA requests comment on the key elements required for such a program. Upon publication of the advance notice of proposed rulemaking (ANPR) in the Federal Register, EPA will begin a 60-day comment period.

Final Rule Banning Consumer Sales

Background

EPA promulgated the final rule under Toxic Substances Control Act (TSCA) Section 6(a). EPA notes that for chemical substances listed in the 2014 update to the TSCA Work Plan for which it completed a risk assessment prior to enactment of the Frank R. Launtenberg Chemical Safety for the 21st Century Act (Lautenberg Act), 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].” Methylene chloride is such a chemical substance. EPA listed methylene chloride in the 2014 update to the TSCA Work Plan. As reported in our September 2, 2014, memorandum, “EPA Releases Final Risk Assessments for Three TSCA Work Plan Chemicals,” EPA’s 2014 final risk assessment includes consumer uses of paint and coating removal, among other uses.

As reported in our February 15, 2017, Monthly Update, on January 19, 2017, EPA proposed under TSCA Section 6(a) risk management restrictions on methylene chloride and N-methylpyrrolidone (NMP). 82 Fed. Reg. 7464. 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 states that it is not issuing a final regulation regarding NMP as part of its action. Instead, EPA will incorporate NMP use in paint and coating removal into the risk evaluation it is currently conducting under TSCA Section 6(b).

**Provisions of the Final Rule**

**Prohibitions and Requirements**

The final rule:

1. Prohibits the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal for all consumer uses;

2. Prohibits the distribution in commerce of methylene chloride in paint and coating removal products to and by retailers. A retailer is 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, he/she must distribute or make available methylene chloride-containing paint and coating removal products solely to commercial or industrial end users or businesses;

3. 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.”; and

4. 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 180 days after the effective date of the final rule. 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.” EPA acknowledges that some individual retailers might not be as efficient with their inventory management, resulting in stranded products and some additional cost for disposal of such products.

Each person who manufactures, processes, or distributes in commerce methylene chloride is required to provide downstream notification of the restrictions in this rule through SDSs, effective 90 days following the effective date of the final rule. 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.”

After 90 days following the effective date of the final rule, each person who manufactures, processes, or distributes in commerce methylene chloride must retain documentation of the entities to whom 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. EPA states that based on a public comment, it added a provision to keep the required records either at the company’s headquarters or at the facility for which the records were generated.

The final rule also includes a definition of retailers and consumer paint and coating removal to be responsive to comments received requesting EPA to provide more clarity regarding the regulated distribution to consumers.

**Downstream Notification**

EPA received four comments related to downstream notification of methylene chloride restrictions, one of which took issue with EPA’s approach. According to EPA, this commenter stated that EPA lacks the authority to require downstream notification and recordkeeping beyond the scope of the conditions of use identified in its unreasonable risk finding. EPA states that while it recognizes there are companies likely manufacturing, processing, or distributing methylene chloride or products containing methylene chloride for uses that will not be regulated under the final rule, it “disagrees with the commenter’s reading of the statute that section 6(a)(3) downstream notification requirements do not apply to conditions of use other than those for which EPA is addressing the unreasonable risk for a chemical substance.”
According to EPA, 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. Further, notification throughout the supply chain streamlines compliance and enhances enforcement, since compliance can be improved when rules are clearly and simply conveyed. Moreover, under Section 6, EPA has authority to require reporting and recordkeeping related to the regulatory requirements imposed by EPA under Section 6.

Some commenters requested more clarity regarding how to use the SDS for downstream notification. In the final rule, EPA specifies the changes to the SDS needed for the downstream notification. Specifically, EPA requires the addition of the following language to sections 1(c) and 15 of the SDS: “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.”

The effective date of the requirement for notification and the associated recordkeeping is 90 days after the effective date of the final rule. EPA notes that the proposed rule would have had these requirements take effect 45 days after the effective date of the final rule. On further reflection, EPA “determined that 90 days is a more reasonable transition period. Regulated entities need only to provide additional information on their SDS, which is routinely produced and updated.”

Import Certification

Persons who import any chemical substance governed by a final TSCA Section 6 rule are subject to the TSCA Section 13 import certification requirements and the corresponding regulations at 19 C.F.R. Sections 12.118 through 12.127; see also 19 C.F.R. Section 127.28. EPA states that 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. The EPA policy in support of import certification is at 40 C.F.R. Part 707, Subpart B. In addition, any persons who export or intend to export methylene chloride are subject to the export notification provisions of TSCA Section 12(b) and must comply with the export notification requirements in 40 C.F.R. Part 707, Subpart D.

Enforcement

TSCA Section 15 makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA Section 6. Therefore, according to EPA, any failure to comply with the final rule when it becomes effective would be a violation of TSCA Section 15. In addition, Section 15 makes it unlawful for any person to: (1) fail or refuse to establish and maintain records as required by the rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) 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.

Training, Certification, and Limited Access for Methylene Chloride

According to the ANPR, one regulatory approach that EPA is considering 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 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
environment, 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 EPA 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 percent of methylene chloride manufactured (including imported) in the U.S. 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.

The notice discusses numerous examples that could serve as models for a training, certification, and limited access regulatory scheme. These include restricted use pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), refrigerant certification under the Clean Air Act (CAA), the Lead-based Paint 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 while others are more limited in their scope.

While EPA welcomes all comments regarding any aspect of a training, certification, and limited access program for methylene chloride for commercial paint and coating removal, EPA specifically requests comments on topics as elaborated in the notice concerning the concept of an integrated program and each of its components. It strikes us that this information, if available and provided to EPA, should provide useful input on the possible strengths and weaknesses of use of this approach in regulating commercial paint and coating uses of methylene chloride.

Training

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. According to EPA, 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 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.

Certification

EPA states that this 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. In the context of the ANPR, 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 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.

Limited Access to Methylene Chloride

EPA states that this component of the program could limit the sale of methylene chloride for paint and coating removal. This 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.

Commentary

EPA is to be congratulated on taking the first final action under TSCA Section 6(a) under the amended law. The final rule provides a clear and comprehensive discussion of the considerations that went into EPA’s regulatory approach in prohibiting the manufacture, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal and in requiring downstream notification by these entities (other than
The final rule, however, does not take action to regulate commercial use of methylene chloride as a remover for paints and coatings. Instead, EPA is soliciting comment via an ANPR 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. Some observers may claim that EPA’s failure to regulate these uses at this time is due to industry bias. It can also be looked at as EPA exercising due diligence in fully considering the “primary alternative regulatory actions” as required under Section 6(c). The ANPR has the effect of increasing the options for such a program that EPA could consider and possibly implement beyond those outlined in the original proposed rule. This is because EPA has 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. We believe that appropriate care and due diligence in considering regulatory options was one 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 think carefully about its chosen regulatory approach and why it was preferred above others.

EPA’s ANPR approach does not preclude a more direct final regulatory action such as a prohibition on the commercial paint and coating stripping uses of methylene chloride, but it may presage a future re-proposal. We recognize that the ANPR approach is a step back in promptly regulating this use of methylene chloride and that developing and implementing such a program could be a complex and difficult undertaking. We, however, believe that this approach may provide a means for stakeholders more fully to understand and appreciate all of the dimensions that are important in achieving a regulation that meets the “to the extent necessary so that the chemical substance no longer presents such risk” requirement as stated in Section 6(a).

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