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Chemicals

Practitioner Insights: TSCA Preemption—Sooner Than Later?

Federal preemption of state chemical laws and regulations was hotly contested during debates on the 2016 amendments to the Toxic Substances Control Act ("TSCA"), Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA"), Pub. Law No. 114-182. In the end, industry and states were left with a complicated but limited form of TSCA preemption, where numerous factors may come into play in determining whether a state chemical control law applies.

Because the U.S. Environmental Protection Agency ("EPA" or "Agency") will be assessing the thousands of chemicals on the market today over many years, likely no more than 20 or so at a time once the program is fully underway, we do not expect to see any significant preemption of state chemical control laws for some time. However, there are already a handful of ongoing, potentially overlapping EPA and state evaluations/proposals involving particular existing chemical substances that could trigger federal preemption questions in the near future. These include 1,4 dioxane, asbestos, hexabromocyclododecane, methylene chloride, N-methylpyrrolidone, decabromodiphenyl ethers, hexachlorobutadiene, and trichloroethylene. Perhaps the most interesting involves efforts by both EPA and the State of California to regulate the use of methylene chloride in paint strippers and, in particular, the interplay between the reformed TSCA and California's Green Chemistry initiative.

Federal and State Action on Methylene Chloride Following the June 22, 2016, passage of the TSCA amendments, EPA initiated two separate actions on methylene chloride: (1) it formally proposed to ban the chemical's use in most paint stripping applications ("Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)"); and (2) it commenced a risk evaluation of all other uses of methylene chloride under its new authorities ("Designation of Ten Chemical Substances for Initial Risk Evaluations Under

the Toxic Substances Control Act." Section 6(b)(2)(A) of TSCA required EPA to commence risk evaluations on ten of the 90 chemicals listed in the Agency's 2014 TSCA Work Plan for Chemicals Assessment ("Work Plan") by December 19, 2016, and the non-paint stripper uses of methylene chloride were selected to be one of those ten. EPA published the initial scope of its risk evaluation for methylene chloride (and the nine other substances in this group) on July 7, 2017.

At the same time, the State of California is preparing targeted risk management measures aimed at restricting the use of methylene chloride in paint strippers. California is taking independent action pursuant to the state's Green Chemistry initiative, also known as the Safer Consumer Products ("SCP") program. The SCP program was created by a 2008 California statute and initial implementing regulations adopted in 2013. In this article, we examine the preemption provisions of the amended TSCA in the context of the contemporaneous federal and state actions on methylene chloride, and the extent to which TSCA's preemption provisions will preclude California from regulating methylene chloride in paint strippers.

The Lautenberg Act's Preemption Mechanisms In general, the new TSCA Section 18 preemption provisions will prohibit the enforcement of any state chemical regulation of a particular substance once EPA both completes a Section 6 risk evaluation for the substance and either: (1) determines that the chemical will not present an unreasonable risk to health or the environment; or (2) concludes that the chemical presents an unreasonable risk under the circumstances of use, and promulgates a rule under Section 6(c) that restricts manufacturing or use of the chemical to mitigate the identified risks. From that point, with certain exemptions discussed below, states are forever prohibited from maintaining existing restrictions or enacting new restrictions on the manufacture, processing, distribution or use of the substance that are different from those imposed by EPA with respect to uses within the scope of EPA's risk evaluation. For example, and subject to certain exemptions, where EPA has concluded that the chemical does not present an unreasonable risk, any state restrictions on uses of the substance

within the scope of EPA's risk evaluation would be barred.

Preemption Pause In addition to permanent preemption at the end of the TSCA Section 6 risk evaluation and risk management process, there is a limited period of temporary preemption that arises during the risk evaluation itself. Referred to as "pause preemption," new state chemical regulations applicable to a substance are prohibited if they are established on or after the date that EPA publishes the scope of the risk evaluation for the substance undergoing formal risk evaluation under Section 6(b)(4). This temporary preemption of new state rules remains in effect until either EPA completes and publishes its formal risk evaluation for the chemical or, if EPA misses the statutory deadline for risk evaluations under TSCA Section 6(b)(4)(G), the date 3½ years after the commencement of the risk evaluation. This protects chemical manufacturers from the burden of new, state requirements for the expected duration of the risk evaluation process, but allows states to enforce their new desired controls for an interim period after formal risk evaluation has been (or should have been) completed, but before the risk management controls (if any) are promulgated and have become effective.

Preemption Pause Exemptions There would be no "pause preemption" for any new state regulation of paint stripping uses of methylene chloride or of uses of any other chemical for which a final risk assessment was issued by EPA under the Work Plan prior to the TSCA amendments. EPA is authorized by Section 26(l)(4) to propose risk management rules for these uses without a separate Section 6 risk evaluation. TSCA Section 18(b)(2) effectively exempts state rules regulating these uses from any "pause preemption" because Section 26(l)(4) permits EPA to proceed to establishing risk management controls without first publishing the risk evaluation scope required under TSCA Section 6(b)(4)(D) that otherwise triggers pause preemption. New state standards for these uses would not be preempted during the development of risk management measures but may be preempted after EPA takes final action, depending on the nature of the underlying state requirement.

Also, exempt from pause preemption are any state standards applicable to a chemical that were established prior to EPA's publication of a TSCA Section 6(b)(4)(D) risk evaluation scope for the substance. "Pause preemption" applies only to new state rules that are established after EPA has published the scope of its intended risk assessment for a chemical. Under Section 18(b)(1), state rules established before that date stay in effect until EPA takes final action after completing the risk evaluation. This provides any interested states a window of as much as six months after EPA determines a substance to be a "high priority substance" to establish new manufacturing or use standards for that substance. If it acts either before or during that window, the state restriction can remain in place at least until EPA takes final action, which may be as long as seven years. (EPA must complete the risk evaluation within three years and risk management controls within an additional four years).

'Grandfather Clause' Preemption Exemption Perhaps the most significant federal preemption exemption for state chemical rules is for certain state chemical regulatory requirements enacted prior to the TSCA amendments. TSCA Section 18(e)(1) generally exempts from potential federal preemption any substance-specific state requirements enacted before April 22, 2016, and also exempts from preemption chemical regulatory action taken on a substance at any time if the action is taken pursuant to a state law that was enacted prior to August 31, 2003 (e.g., California's Proposition 65). 15 U.S.C. § § 2617(e)(1)(A), (B). State rules in these categories are never preempted under TSCA Section 18 and remain in effect even after EPA takes final action on a chemical.

Other Types of State Chemical Rules Exempt from Preemption There are several other classes of state chemical control requirements that are not subject to TSCA preemption. These include: (1) state laws that impose only reporting, monitoring, or information obligations; and (2) environmental laws that regulate air quality, water quality, or hazardous waste treatment or disposal. Moreover, states can apply to EPA for rule-specific waivers from either the preemption pause or permanent preemption. As to the latter, the state must make several showings in its application, such as that the state law is grounded in sound science and that the waiver will not unduly burden interstate commerce. EPA has discretion whether or not to grant the waiver from permanent preemption. 15 U.S.C. § 2617(f).

Thus, except to the extent 'pause preemption' applies, states generally will remain free to maintain existing use controls and impose new bans or restrictions on individual chemicals, at least until EPA completes a risk evaluation of relevant uses of the chemical and takes any appropriate risk management actions. Even where the Agency has acted, whether state rules are preempted (and the scope of any preemption) depends on a number of factors, including principally the timing of a state's legislation or rules.

TSCA Preemption and California's Green Chemistry Regulations Application of TSCA's preemption grandfather clause will be a straight-forward exercise in most instances, such as when a state has regulated "a specific chemical substance" within its borders prior to the first grandfather date of April 22, 2016, or when it has regulated a specific chemical after that date but pursuant to a statute enacted prior to the second grandfather date of August 31, 2003. In those cases, the state regulation would be grandfathered and not subject to TSCA preemption. So-called state Green Chemistry laws enacted after 2003, however, may raise more difficult questions. State Green Chemistry laws and regulations often do not impose restrictions on a specific chemical; in many cases, they establish a legal framework for a state agency to designate and impose restrictions on individual chemicals and uses in the future. This raises the question whether chemical-specific regulations issued after April 22, 2016 pursuant to a law adopted before that date are subject to preemption or protected by the grandfathered clause.

This scenario may soon play out. Under California's SCP program, the Department of Toxic Substances Control ("DTSC") is designating "Priority Products" that contain particular "Chemicals of Concern"

(“CoC”) (e.g., methylene chloride in paint strippers). The manufacturers (and potentially retailers) of designated Priority Products may be subject to substantial regulatory requirements, potentially including state use restrictions on particular chemicals, such as limits on the amount or concentration of a chemical in a product, use restrictions to reduce exposures to the chemical, or a complete ban on the Chemical of Concern / product combination. See Cal. Code Regs. tit. 22 § § 69506.4, .5. To date, the DTSC has proposed (to different degrees) to regulate three such products, including paint strippers containing methylene chloride. As noted, under TSCA Section 6(a), EPA also has proposed to regulate use of methylene chloride paint strippers. If both EPA and DTSC issue methylene chloride paint stripper regulations, will the California regulations be preempted?

It might be argued that it is sufficient for preemption protection that the California SCP statute and general implementing regulations were adopted before the April 22, 2016, grandfather date, even if a specific regulation of methylene chloride use is not enacted until after the grandfather date. Indeed, DTSC arguably acted to signal its *intent* to regulate methylene chloride in some manner prior to the grandfather date when it formally designated the chemical as a Candidate Chemical for regulatory action in 2013.

However, we believe the better view is that SCP chemical-specific requirements first adopted after the grandfather date would not be exempt from preemption and would be preempted to the extent the California requirements prohibit or otherwise restrict manufacturing, processing, distribution in commerce, use or disposal of methylene chloride with respect to uses within the scope of EPA’s risk evaluation(s). Grandfather protection only applies to state “action[s] taken” or “requirement[s] imposed” or “enacted” with respect to a particular chemical substance prior to the grandfather date. General program framework regulations that do not regulate any particular chemical are not enough. Similarly, mere listing of a “Candidate Chemical” does not impose any state requirements that might be preserved.

Regardless, if California were to adopt rules regulating use of methylene chloride in paint strippers before EPA’s pending risk management rule for that same use is finalized and effective, the California rules would not be subject to pause preemption, and could remain in effect until EPA’s final risk management rule for that use became effective. Paint stripper use of methylene chloride was the subject of a risk assessment completed under the Work Plan before the TSCA amendments. Thus, EPA never issued a TSCA Section 6(b)(4)(D) risk evaluation scope for the paint stripper use and state regulation of that use is not subject to pause preemption. Moreover, EPA has now issued a risk evaluation scope for other uses of methylene chloride. If California were to establish use restrictions under the SCP program on any other methylene chloride use covered by EPA’s risk evaluation scope, the California restrictions would be subject to pause preemption, as well as permanent preemption once any risk management rule became effective.

As to other potential exemptions, the initial obligations for manufacturers of products formally designated as “Priority Products” under the California SCP

regulations might well be deemed “informational” and exempt from preemption by TSCA Section 18(d)(1)(A)(ii). Once a Priority Product is listed, manufacturers first notify DTSC of their status and, absent an applicable exemption, must then perform an elaborate alternatives analysis to assess possible measures to reduce potential exposure and risk of harm to public health and the environment. California would not act to restrict manufacture, processing, distribution in commerce, or use of the COC in the product, if at all, until the end of the process, after the alternatives analysis is completed. TSCA only preempts state action that prohibits or restricts manufacturing, processing, distribution in commerce, use or disposal of a chemical.

While this underscores that even a formal listing as a SCP Priority Product before the grandfather date would not seem to be sufficient to prevent subsequent preemption, it also suggests that states may retain some portion of whatever authority they may have under state law to compel risk analysis, data development, and other “information” obligations. However, this potential authority is not unlimited. TSCA Section 18(a)(1)(A) specifically preempts state administrative actions to compel development of information about a substance to the extent duplicative of information required to be developed under TSCA Sections 4, 5 or 6.

Of course, for such a dispute to arise, EPA must finalize a Section 6(a) risk management rule and California’s DTSC must conclude that its own restrictions are still warranted after paint stripper manufacturers have conducted the required alternatives analysis for methylene chloride. Cal. Code Regs. tit. 22 § § 69501, 69505. Alternatively, California could ask EPA to grant a waiver under Section 18(f) or DTSC could issue a discretionary exemption under its own regulations from SCP obligations if there were either a direct conflict between its rule and EPA’s regulation, or where there is substantial overlap between the two. Cal. Code Regs. tit. 22 § § 69501, 69506.9.

Conclusion The scope of preemption as applied to California’s efforts to regulate methylene chloride is just one of numerous examples of how the amended TSCA may intersect state laws. Industry must pay close attention to all of the nuances of TSCA Section 18—the grandfather clause, statutory exceptions, discretionary and mandatory state waivers, low- or high-priority designations, and the timing of any action taken by EPA and the states—to adequately determine whether there is any preemptive effect.

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