

CHEMICALS

TSCA

How EPA assesses and regulates chemicals under the amended Toxic Substances Control Act has a number of implications for workplace and consumer safety. In particular, chemicals regulated under other environmental statutes may bear on EPA's plans in this arena. W. Caffey Norman with Squire Patton Boggs explores these inter-relationships as EPA begins implementing the new law.

Implementation of TSCA Section 6: EPA Moving in the Wrong Direction?



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The opinions expressed here do not represent those of Bloomberg BNA, which welcomes other points of view.

Introduction

EPA has not regulated a chemical under TSCA Section 6, which provides for regulation of existing as opposed to new chemicals, since 1989, when it adopted a ban on asbestos which was subsequently overturned by a federal Court of Appeals. This 27-year hiatus appears to be coming to an end, as EPA has indicated that it expects to propose three such rules by late 2016. As part of these rulemakings, EPA convened Small Business Advocacy Reviews (SBARs) on June 15, 2016. These SBARs were for trichloroethylene (TCE) in

vapor degreasing and for methylene chloride (dichloromethane or “DCM”) and n-methyl pyrrolidone in paint stripping. Although such an SBAR would seem equally necessary under the Regulatory Flexibility Act for the third rulemaking (TCE in spot cleaning and aerosol spray degreasing), no such panel has yet been convened.

This article reviews how EPA is approaching implementation of TSCA Section 6 in light of its presentations at these meetings, and previews how EPA will move forward in the new legal landscape following enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016. It should be of particular relevance to manufacturers of basic commodity chemicals, such as chlorinated hydrocarbons and formaldehyde.

Work Plan Assessments and TSCA Section 9

Suprisingly, the focus of EPA’s SBAR presentations was occupational exposure. Based on Work Plan Assessments released in June 2014 (TCE) and August 2014 (DCM), EPA identified many occupational exposure scenarios that exceeded the target cancer risk range of 1×10^{-6} . For TCE, EPA derived an acceptable exposure limit (AEL) of 0.4 parts per billion (ppb) as an eight-hour time-weighted average (TWA). For DCM, EPA derived a cancer AEL of 0.2 parts per million (ppm) as an eight-hour TWA. For TCE it also identified non-cancer risks to workers for a range of human health effects, most notably cardiac anomalies in offspring, and a remarkably low non-cancer AEL of 1 ppb, also as an eight-hour TWA, for acute exposures. The non-cancer AEL derived by EPA for acute exposures to DCM was 1.3 ppm.

Occupational/Consumer Exposure Regulated.

The AELs derived by EPA are below (three of them orders of magnitude below) current workplace limits. The Occupational Safety and Health Administration (OSHA) has regulated occupational exposure to TCE and DCM for many years. For TCE, the permissible exposure limits (PELs) are 100 ppm as an eight-hour TWA, 200 ppm as an acceptable ceiling concentration, and 300 ppm as an acceptable maximum peak (five minutes in any two-hour period) above the acceptable ceiling concentration for an eight-hour shift. TCE producers recommend compliance with the Threshold Limit Values (TLVs) developed by the American Conference of Governmental Industrial Hygienists. For TCE, the current TLVs are 10 ppm as an eight-hour TWA and 25 ppm as a Short-Term Exposure Limit.

For DCM, in 1997 OSHA adopted a comprehensive standard under Section 6(b)(5) of the Occupational Safety and Health Act (OSH Act) lowering the workplace exposure limit for DCM from 500 ppm to 25 ppm as an eight-hour TWA. In addition, it established a short-term (15-minute) exposure limit (STEL) of 125 ppm and an action level for concentrations of airborne DCM of 12.5 ppm (eight-hour TWA).

As justification of its emphasis on the workplace, EPA indicated to the small business representatives that it has authority to regulate occupational hazards because the authority of OSHA extends only to *private* sector employers. Thus, *public* sector employees would not be subject to OSHA jurisdiction. While true, this has been the case since enactment of the OSH Act in 1970, preceding the enactment of TSCA by six years. It had not previously been suggested that this limitation on OSHA’s authority would give EPA jurisdiction over all workplaces. Further, according to EPA, OSHA has no plans to revise its PELs for these compounds, while EPA’s TSCA authority includes addressing toxic chemicals that cut across worker, public sector, and consumer settings.

EPA produced a letter (undated but thought to have been issued on or about April 4, 2016) from David Michaels, Assistant Secretary for Occupational Safety and Health, to James Jones, EPA’s Assistant Administrator for Chemical Safety & Pollution Prevention, which states “[g]iven certain limitations imposed on OSHA’s authority under the OSH Act, this Agency believes TSCA provides the EPA with a means of eliminating or reducing the risks associated with these chemical uses in a more coordinated fashion across both consumer and occupational settings.” The letter does not indicate how or why Assistant Secretary Michaels, whose department has no jurisdiction outside the workplace, was authorized to address consumer exposures.

As to consumer exposure, EPA’s concern about DCM use in paint stripping arose from reports of over a dozen asphyxiations of individuals stripping bathtubs. In addition to its concern about occupational exposure, EPA disclosed in the SBAR for paint stripping that it is considering restricting sales of DCM to 55-gallon drums. This would eliminate the sale of DCM-based paint strippers to consumers and eliminate much of the commercial refinishing market as well. Here EPA appears to be prepared to act without reference to the Federal Hazardous Substances Act (FHSA), which grants jurisdiction over household products containing hazardous substances to the Consumer Product Safety Commission (the Commission or CPSC).

In 1987, the Commission adopted cautionary labeling for household products containing DCM, including paint strippers, that would meet or exceed the requirements of the FHSA. (Labeling of Certain Household Products Containing Methylene Chloride; Statement of Interpretation and Enforcement Policy (hereafter the “Statement”), 52 Fed. Reg. 34698 (September 14, 1987).) Under the FHSA, further regulation of these household products is precluded absent a finding that the cautionary language contained in the Commission’s Statement is ineffective. The Commission has received a petition requesting that it strengthen the label to address the acute over-exposure as well as the chronic hazard, and Commission staff recently gave its approval to cautionary language that warns against using such products to strip bathtubs.

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It is odd that EPA has chosen DCM for its one of its inaugural rulemakings under the Lautenberg Act, even though it has already addressed DCM under a different (and substantially unchanged) provision of TSCA. Specifically, Section 4(f) requires EPA, upon receipt of information which indicates that “there may be a reasonable basis to conclude” that a chemical “presents a significant risk of serious or widespread harm,” to initiate action under TSCA 5, 6, or 7. Based on information that it had received in 1985, EPA initiated a priority review of risks of human cancer from exposures to DCM by announcing that it would be conducting, in consultation with other federal agencies, a comprehensive and integrated regulatory investigation. (50 Fed. Reg. 42037 (October 17, 1985).) Thereafter, EPA described the risk management actions completed by OSHA and CPSC, and reported on how “the integrated regulatory investigation led to significant exposure reductions in the major chlorinated solvent use applications, and established a precedent for future cooperative regulatory endeavors.” (56 Fed. Reg. 24811 (May 31, 1991).) The information that EPA received in 1985 was the preliminary findings of the cancer bioassay that is the basis of its current cancer AEL. The only new scientific information is relevant to non-cancer effects (the asphyxiations of individuals stripping bathtubs), and as noted above is already being addressed by CPSC in a much more targeted fashion.

Environmental Exposure Already Regulated.

It is also a matter of concern that neither the TCE nor the DCM Work Plan assessment makes use of voluminous information on the very uses of concern that are already required to be reported to EPA. The TCE Work Plan assessment uses the incorrect baseline for exposure to TCE from vapor degreasing, because all of the exposure data in the assessment were collected long before the May 2010 compliance deadline established in the 2007 National Emission Standard for Hazardous Air Pollutants (NESHAP) for Halogenated Solvent Cleaning. This comprehensive regulation of vapor degreasing imposed a 7 tons per year facility-wide limit on TCE emissions, changed work practices, and greatly reduced both in-facility (occupational and bystander) exposure and fenceline emissions (see 40 C.F.R. Part 63, Subpart T; 72 Fed. Reg. 25138 (May 3, 2007)). Most significantly, it requires detailed reporting to EPA from 2010 onward, for all covered degreasers, of TCE consumption, emissions, controls, and other such information of direct relevance to EPA’s exposure assessment, which has so far been completely ignored by EPA (40 C.F.R. § 63.471(e),(f),(g),(h)).

Similarly, EPA’s DCM Work Plan assessment does not reflect workplace conditions following implementation of EPA’s NESHAP for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources. (40 C.F.R. Part 63, Subpart HHHHHH; 73 Fed. Reg. 1738 (Jan. 9, 2008).) This regulation requires each paint stripping operation to minimize the evaporative emissions of DCM, to evaluate each application to ensure there is a need for paint stripping, to evaluate each application where a paint stripper containing DCM is used to ensure that there is no alternative paint stripping technology that can be used, to reduce exposure of all paint strippers containing DCM to the air, and the like (40 C.F.R. 63.11173). Each paint stripping operation must maintain copies of annual usage of paint strippers

containing DCM on site at all times, and if it has annual usage of more than one ton of DCM must develop and implement a written plan to minimize the use and emissions of DCM.

Section 112 of the Clean Air Act, under which these standards were adopted, requires that they must ensure an “ample margin of safety to protect public health.” Thus, if the risk of concern were significant, EPA would have to adopt more protective standards under the Clean Air Act. It is regrettable that EPA’s Work Plan assessments for TCE and DCM for these very applications fail to start with the detailed study and analysis of these sources already carried out by another part of EPA.

TSCA Section 9.

As originally enacted and as updated by the Lautenberg Act, TSCA Section 9(d) requires EPA to consult and coordinate with other federal agencies “for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes.” Worker and consumer health and safety fall under the jurisdictions, respectively, of OSHA and CPSC. The uses of TCE in vapor degreasing and DCM in paint stripping are already more than adequately regulated under the OSH Act and/or the FHSA. This comprehensive regulatory framework provides adequate protections with respect to the same potential adverse impacts and potential exposure pathways targeted by the current EPA initiative. Taking steps that may lead to the removal of products from the marketplace because workers or consumers failed to comply with the existing legal requirements is not consistent with TSCA either as initially enacted or as revised.

The basis for EPA’s broad assertion of jurisdiction over occupational and consumer use is unclear. The Lautenberg Act eliminated the requirement in TSCA Section 6(a) that EPA protect “against [unreasonable] risk using the least burdensome requirements,” but did not materially change the existing framework that requires unreasonable risks to be addressed under statutory authority other than TSCA wherever possible. EPA’s longstanding interpretation of this framework is as follows:

“Under section 9(a)(1) of TSCA, the Administrator is required to submit a report to another Federal agency when two determinations are made. The first determination is that the Administrator has reasonable basis to conclude that a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The second determination is that the unreasonable risk may be prevented or reduced to a sufficient extent by action taken by another Federal agency under a Federal law not administered by EPA. Section 9(a)(1) provides that where the Administrator makes these two determinations, EPA must provide an opportunity to the other Federal agency to assess the risk described in the report, to interpret its own statutory authorities, and to initiate an action under the Federal laws that it administers.

“Accordingly, section 9(a)(1) requires a report requesting the other agency: (1) To determine if the risk may be prevented or reduced to a sufficient extent by action taken under its authority, and (2) if so,

to issue an order declaring whether or not the activities described in the report present the risk described in the report.

“Under section 9(a)(2), EPA is prohibited from taking any action under section 6 or 7 with respect to the risk reported to another Federal agency pending a response to the report from the other Federal agency. There would be no similar restriction on EPA for any risks associated with a chemical substance or mixture that is not within the section 9(a)(1) determinations and therefore not part of the report submitted by EPA to the other Federal agency.” (4,4'-Methylenedianiline; Decision to Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 27674 (July 5, 1985). EPA also has acted under Section 9(a) to refer 1,3-butadiene and glycol ethers to OSHA, 50 Fed. Reg. 41393 (Oct. 10, 1985) and 51 Fed. Reg. 18488 (May 20, 1986), respectively, and to refer dioxins in bleached wood pulp and paper products to the Food and Drug Administration, 55 Fed. Reg. 53047 (Dec. 26, 1990).)

TSCA Section 9(b) is the intra-agency counterpart to Section 9(a). It requires EPA to “coordinate” actions taken under TSCA with actions taken under other statutes administered by EPA. If EPA determines that a chemical risk “could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk,” unless she determines that “it is in the public interest” to proceed under TSCA. Indeed, the Lautenberg Act strengthened TSCA Section 9(b) by moving into it a provision formerly in TSCA Section 6 requiring EPA, in making such a public interest determination, to compare “the estimated costs and efficiencies of the actions to be taken under [TSCA] and an action to be taken under such other law.”

It was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. When TSCA was enacted in 1976, Representative James Broyhill of North Carolina indicated that “it was the intent of the conferees that the Toxic Substance Act not be used, when another Act is sufficient to regulate a particular risk.” (122 Cong. Rec. H11344 (Sept. 28, 1976).) TSCA Section 9(a) is substantively unchanged by the Lautenberg Act. The House Energy and Commerce Committee Report states: “H.R. 2576 reinforces TSCA’s original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals,” and further clarifies that “while Section 5 makes no amendment to TSCA Section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety.” (H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28. Cf. Detailed Analysis and Additional Views of Senators Boxer, Markey, Udall, and Merkley, “13. TSCA As the Primary Statute for the Regulation of Toxic Substances . . . EPA’s authorities and duties under Section 6 of TSCA have been significantly expanded under the [Lautenberg Act] . . . The interagency referral process and the intra-agency consideration process established under Section 9 of existing TSCA must now be regarded in a different light since TSCA can no

longer be construed as a ‘gap-filler’ statutory authority of last resort.” 162 Cong. Rec. S3517 (June 7, 2016).)

Colloquies on the floor of the House of Representatives make this intent clear with specific reference to TCE and DCM, most notably the following:

“Mr. SHIMKUS. Mr. Speaker, I yield 2 minutes to the gentlewoman from Tennessee (Mrs. Blackburn), the vice chair of the full committee.

Mrs. BLACKBURN. Mr. Speaker, I do rise in support of the amendments to H.R. 2576, and I congratulate Chairman Shimkus on the wonderful job he has done. Mr. Speaker, I yield to the gentleman from Illinois (Mr. Shimkus) for the purpose of a brief colloquy to clarify one important element of the legislation.

Mr. Chairman, it is my understanding that this bill reemphasizes Congress’ intent to avoid duplicative regulation through the TSCA law. It does so by carrying over two important EPA constraints in section 9 of the existing law while adding a new, important provision that would be found as new section, 9(b)(2).

It is my understanding that, as a unified whole, this language, old and new, limits the EPA’s ability to promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA.

Would the chairman please confirm my understanding of Section 9?

Mr. SHIMKUS. Will the gentlewoman yield?

Mrs. BLACKBURN. I yield to the gentleman from Illinois.

Mr. SHIMKUS. The gentlewoman is correct in her understanding.

Mrs. BLACKBURN. I thank the chairman. The changes you have worked hard to preserve in this negotiated bill are important. As the EPA’s early-stage efforts to regulate methylene chloride and TCE under TSCA statute section 6 illustrate, they are also timely.

EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New section 9(b)(2) will force the Agency to do just that.

I thank the chairman for his good work.” (162 Cong. Rec. H3028 (May 24, 2016).)

Work Plans and TSCA Sections 6, 26

EPA appears ready to push its authority into the workplace and consumer uses even though TSCA Sec-

tion 9's limits on this authority were strengthened. On the other hand, although significant changes were made to ensure that EPA would employ the "best available science" in its risk assessments, EPA seems poised to rely on remarkably sketchy and inadequate assessments in its inaugural rulemakings under TSCA Section 6.

TSCA Section 6(b)(4)(F), as revised by the Lautenberg Act, requires that EPA's risk evaluations must, among other things:

- "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;"
- "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance;" and
- "describe the weight of the scientific evidence for the identified hazard and exposure."

New TSCA Section 26(h) requires that, in carrying out Section 6, "to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

- (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
- (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
- (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models."

With regard to the Work Plan assessments completed prior to passage of the Lautenberg Act, the subject of this article, TSCA Section 26(l)(4) provides that "the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6." Thus, EPA may base regulation on the pre-

enactment risk assessments only to the extent that they comply with the substantive requirements above.

While this is not the place for an extensive analysis of the shortcomings of these assessments, a few examples may suffice:

- The TCE Work Plan assessment expressly relies on hazard values derived directly from a single academic study to estimate non-cancer risk, even though several other studies, including two Good Laboratory Practice-compliant studies conducted under EPA guidelines, have been unable to reproduce the effect; the academic study has been heavily criticized in the published literature; other regulatory agencies have expressly declined to rely on the academic study citing data quality concerns; the authors of the study have published repeated corrections that fail to address the data quality concerns; and a majority of EPA's own staff scientists expressed "low" confidence in its results.
- Both assessments relied on out-of-date exposure scenarios that did not take into account changes in workplace emissions and exposures as a result of adoption and implementation by EPA of the NES-HAPs described above. Indeed, the DCM assessment relies upon data that preceded the 20-fold reduction in permitted workplace levels (from 500 ppm to 25 ppm) that resulted from adoption of the OSHA workplace standard in 1997.
- Both assessments are screening level assessments which do not meet Office of Management and Budget guidelines implementing the Information Quality Act for a "highly influential scientific assessment" to support TSCA Section 6 rulemaking. Both assessments employed a cascade of worst-case or default assumptions that led to overestimation of potential risks. Such assessments may be appropriate to support a decision that no further action or evaluation is necessary, because there is confidence that the potential risks are not a concern. However, they are considered inappropriate to support regulations intended to reduce risk because screening level assessments do not accurately estimate risk or quantify exposures.
- The report of the peer review of the TCE assessment highlights the foregoing points in the clearest possible terms, but EPA has to date ignored it. In fact, the EPA Assistant Administrator for Chemical Safety and Pollution Prevention wrote to the EPA Inspector General that "[i]t is notable that the external peer reviews of all the Work Plan assessments we have completed thus far supported our overall assessment methodologies and conclusions." (Response to Office of Inspector General Draft Report No. OPE-FY14-0012 "EPA's Risk Assessment Division Has Not Fully Adhered to Its Quality Management Plan," (July 30, 2014), Appendix A, p.10 (available at <https://www.epa.gov/sites/production/files/2015-09/documents/20140910-14-p-0350.pdf>) . Compare BNA Daily Environment Report, "EPA Peer Reviewers Say Trichloroethylene Analysis Not Ready for Regulatory Use" (July 18, 2013).)

Following enactment of the Lautenberg Act, it should be clear that a risk evaluation that supports a TSCA Section 6 rule must be more robust than the screening level Work Plan assessments that EPA conducted for TCE and DCM. Peer review and public comments identified numerous scientific deficiencies with the draft Work Plan assessments, including the inappropriate use of default assumptions; ignoring contrary evidence that affects the weight of the scientific evidence; reliance on inappropriate exposure data; conclusions inconsistent with the evidence cited; and reliance on a study that is not reproducible. Equally important shortcomings in both the hazard and exposure assessments were noted. Whatever “best available science” may mean, it cannot include reliance on an unreproducible toxicity study or outdated exposure information. And certainly EPA can no longer afford to ignore the conclu-

sions of the peer review it initiated, as it must consider “the extent of independent verification or peer review of the information.”

Implications for Other Chemicals

There is nothing unique or unusual about TCE or DCM that would limit EPA’s apparent over-reaching to their uses. EPA initially targeted them because of concerns about consumers and small workplaces, but is now looking at much broader regulation. EPA has derived cancer potency factors for dozens of widely used compounds (the table** below shows EPA’s cancer potency factors for six other such chemicals, selected at random). Most if not all such substances would effectively be banned from the workplace under the approach EPA is considering.

| Chemical | Units for AELs and PELs | OSHA PEL * | Cancer AEL | PEL/Cancer AEL |
|-------------------------|-------------------------|------------|------------|----------------|
| Benzene | ppm | 10 | 0.00031 | 32,505 |
| Beryllium and compounds | mg/m ³ | 0.002 | 0.0000032 | 626 |
| Butadiene, 1,3 - | ppm | 1 | 0.00012 | 8,660 |
| Formaldehyde | ppm | 0.75 | 0.00048 | 1,561 |
| Lead and Compounds | mg/m ³ | 0.05 | 0.00064 | 78 |
| Methylene Chloride | ppm | 25 | 0.2 | 113 |
| Trichloroethylene | ppm | 10 | 0.00035 | 28,659 |
| Vinyl Chloride | ppm | 1 | 0.00068 | 1,467 |

* Cal PEL for lead and compounds, ACGIH TLV for TCE

**The author acknowledges with appreciation the assistance of Rick Reiss and Paul Turnham of Exponent in preparing the table above.