EPA Implementation of TSCA § 6 Poses Risks for Coatings Industry

W. Caffey Norman, *Contributing Writer*

EPA last regulated a chemical under Toxic Substances Control Act (TSCA) § 6, which provides for regulation of existing as opposed to new chemicals, in 1989. This 28-year hiatus may be coming to an end, with the proposal of three such rules in the month before the inauguration of President Trump. While the new Administration may never adopt the proposed rules, the approach to implementing § 6 that they reflect should be of great concern to formulators, chemical manufacturers, and manufacturing industry generally.

Proposed Rules

First, EPA proposed to ban the use of trichloroethylene (TCE) in aerosol degreasing and in spot cleaning by dry cleaning facilities (81 Fed. Reg. 91592 (Dec. 16, 2016)). Thereafter, on the day before inauguration, EPA proposed to ban use of TCE in vapor degreasing (82 Fed. Reg. 7432 (Jan. 19, 2017) and to ban use of methylene chloride (dichloromethane or DCM) in paint stripping (82 Fed. Reg. 7464 (Jan. 19, 2017).

Each of these rules was proposed under the authority of TSCA § 6(a), as amended in June 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act"), based on risk assessments completed in 2014. While EPA is authorized under TSCA § 26(l)(4) to regulate based on a risk assessment completed before TSCA was revised, the statute is very clear that any such rule must fall within the scope of the assessment and that EPA must comply with all "applicable" requirements of TSCA § 6. Industry commenters have detailed the deficiencies in these proposals, and recommended that EPA instead consider these uses as part of mandated risk assessments beginning later this year for ten priority compounds recently designated by EPA under TSCA § 6(b)(2)(A), which include TCE and DCM. The concern is that adoption of these proposals would greatly expand EPA's authority and would be inconsistent with the "best available science" requirements of the Lautenberg Act.

Occupational and Consumer Exposure

Surprisingly, the proposed rules focus on occupational and consumer exposures, long considered to be the province of the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC), respectively. The basis for EPA's broad assertion of jurisdiction over occupational and consumer uses is unclear. The Lautenberg Act eliminated the requirement in TSCA § 6(a) that EPA protect "against [unreasonable] risk using the least burdensome requirements," and included a new requirement that EPA determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. . . including an unreasonable risk to a potentially exposed or susceptible subpopulation," defined to include workers. But the Lautenberg Act did not materially change the existing framework that requires unreasonable risk to be addressed under statutory authority other than TSCA wherever possible.

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Based on the 2014 assessments, EPA identified many occupational exposure scenarios that exceeded its target cancer risk range. For TCE, EPA derived an acceptable exposure limit (AEL) of 0.4 parts per billion (ppb) as an eight-hour time-weighted average (TWA). This is 250,000 times lower than the current OSHA permissible exposure limit (PEL) of 100 ppm. For DCM, EPA derived a cancer AEL of 0.2 ppm, over 100 times lower than the 25 ppm limit set by OSHA when it adopted a comprehensive standard for the substance.

EPA's asserted justification for this newfound authority to regulate occupational hazards was that OSHA's jurisdiction does not extend to all state and local government employees, self-employed workers, military personnel and certain other employees. EPA produced a letter from David Michaels, then Assistant Secretary for Occupational Safety and Health, to James Jones, then EPA Assistant Administrator for Chemical Safety and Pollution Prevention, which stated "[g]iven [these] 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."

While OSHA's jurisdiction has been so limited since enactment of the Occupational Safety and Health Act in 1970, which preceded enactment of TSCA by six years, it had not been previously suggested that this limitation on OSHA's authority gives EPA jurisdiction over hazardous chemicals in the workplace. Moreover, as these limitations are universally applicable, EPA would supplant OSHA's workplace authority over use of all hazardous chemicals in the workplace.

With regard to DCM in paint stripping, EPA went even further, proposing to restrict sales to 55-gallon drums in order to reduce consumer exposure. This would eliminate sale of DCM-based paint strippers to consumers at Lowe's and Home Depot and decimate the commercial refinishing market as well. Here EPA proposed to act without reference to the Federal Hazardous Substances Act, pursuant to which the Consumer Product Safety Commission (CPSC) has issued a Statement of Enforcement Policy that specifies uniform cautionary labelling for all household products containing methylene chloride. Further, in June 2017 the CPSC announced that it will be revising the Statement of Enforcement Policy to strengthen the labelling requirements.

TSCA § 9

As originally enacted, and updated by the Lautenberg Act, TSCA § 9 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."

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 [Control] 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).

Colloquies on the floor of the House of Representatives make this intent clear with specific reference to TCE and DCM. 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 the original or revised version of TSCA.

New Science Requirements -- TSCA §§ 6, 26

EPA proposed to expand its authority into the workplace and consumer uses even though TSCA § 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, the EPA proposals rely on remarkably sketchy and inadequate assessments.

The substantive "best available science" requirements of TSCA §§ 6 and 26 include making decisions based on the weight of the scientific evidence, taking into account peer review, and the like. Following enactment of the Lautenberg Act, it should be clear that a risk evaluation that supports a TSCA § 6 rule must be more robust than the screening level assessments that EPA conducted for TCE and DCM in 2014.

The numerous scientific deficiencies identified by peer review and public comments include:

- the inappropriate use of default assumptions;
- ignoring contrary evidence or "cherry picking," instead of basing conclusions on the weight of the scientific evidence;
- reliance on inapposite exposure data;
- conclusions inconsistent with the evidence cited; and
- reliance on a study that is not reproducible.

Implications for Other Chemicals

There is nothing unique or unusual about TCE or DCM that would limit EPA's 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. Most if not all such substances would effectively be banned from the workplace and consumer products if the approach reflected in the proposed bans were adopted. For example, the AEL for vinyl chloride using EPA's approach would be 0.7 ppb, for formaldehyde 0.5 ppb, in each case some 1500 times or more lower than the OSHA PEL.

Going forward, it is important that new approaches to the accepted EPA methodology for cancer risk assessment be developed. This methodology is based on models developed to assess cancer risk from ionizing radiation. Under this linearized non-threshold model, radiation is always considered harmful, there is no safe exposure, and biological damage caused by ionizing radiation (essentially the cancer risk) is directly proportional to the amount of radiation exposure to the human body (response linearity). The scientific basis for applying these assumptions to low-level radiation is under review by the Nuclear Regulatory Commission (80 Fed. Reg. 35870 (June 23, 2015), and consideration of the direct applicability of this approach to low-dose chemical carcinogenesis is long overdue. More narrowly, the circumstances in which non-linear or threshold mechanisms may account for increased cancer incidence in high-dose cancer bioassays, and species differences in metabolism and pharmacokinetics, need to be carefully evaluated and, where relevant, taken into account in EPA's cancer risk assessments. **CW**

W. Caffey Norman *is a partner in the Washington DC office of Squire Patton Boggs. Caffey's environmental practice focuses on the regulation of hazardous chemicals by the Environmental Protection Agency, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and various state regulatory agencies. He has been particularly active in the subject areas of toxic substances, stratospheric ozone depletion, and global warming. For many years Caffey has developed and successfully implemented strategies to defend products targeted for phase out or use reduction. He has participated in EPA rulemakings to regulate hazardous substances under all the environmental statutes and has initiated legislative and judicial review of a number of EPA regulations. Caffey also represents a number of industry task forces in connection with pesticide registration and the negotiation of test rules and testing consent orders.*