

The US EPA is tightening chemical regulation even before TSCA Reform, says Stephen A. Owens of global law firm Squire Patton Boggs

In June, the US House of Representatives passed landmark legislation to reform the decades-old Toxic Substances Control Act (TSCA). The Senate will also soon vote on a TSCA reform bill. If a 'modernised' TSCA eventually becomes law, the regulation of chemicals in the US could be changed dramatically.

The importance of TSCA reform legislation cannot be overstated. But the steps that the US Environmental Protection Agency (EPA) already is taking to tighten chemical regulation in the United States should not be overlooked. Even in the absence of a revised TSCA statute, the EPA has already begun to prioritise chemicals for review, conduct chemical risk assessments and impose new restrictions on chemicals to ensure their safe use – just as the TSCA reform bills in Congress would require it to do.

Since the beginning of the Obama administration, the EPA has been moving to use its existing TSCA authority more aggressively. During the early years, from 2009 to 2011, it issued ten 'Action Plans' on chemicals or groups of chemicals that the EPA determined warranted evaluation and potentially additional regulation. In many respects, these plans formed the basis for the agency's current efforts under TSCA.

Also during 2011, the EPA issued a background document discussing its plans for identifying a larger group of chemicals for review and assessment and laid out criteria for selecting priority chemicals for review from among the roughly 85,000 chemicals presently on its TSCA Inventory. This is also similar to what the TSCA reform bills would require the EPA to do.

Work Plan Chemicals List

Using these criteria, in March 2012, the EPA unveiled a list of 83 priority chemicals (designated as 'Work Plan' chemicals) that it targeted for risk assessments and possible regulation in the next few years. In addition, it released a 'Methods Document' that explained how it prioritised these particular chemicals.

First, the agency reviewed a wide range of internal and external data sources and identified 1,235 chemicals that met one or more of six factors: being identified as potentially of concern for children's health, as persistent, bioaccumulative and toxic, or as probable or known carcinogens, being used in children's or consumer products or having been detected in biomonitoring programmes.

The EPA then reduced the list to 345 by excluding chemicals which are regulated under other federal laws (such as pesticides), those which generally do not present significant health hazards (such as polymers) and those which are already addressed in the Action Plans or which are already subject to extensive regulation (such as PCBs). Additionally, metals and their compounds were grouped together, rather than identified separately.

Each of the 345 chemicals was then assigned a score based on three characteristics: hazard, exposure and potential for persistence and/or bioaccumulation. The 83 'Work Plan' chemicals scored highest using these factors.

When the EPA announced the Work Plan chemicals list, it also stated that it would conduct risk assessments on seven of the chemicals during 2012, with assessments for others to follow. In October 2014, it updated the list by adding 23 new chemicals to it and removing or consolidating 16 others, based on newly received production data and other information. The update brought the total number of Work Plan chemicals to 90.

The Work Plan is essentially a list of 'priority' chemicals identified by the EPA. Recognising the analysis that went into developing the list, both the House and Senate TSCA reform bills include specific references to the Work Plan in connection with the chemical prioritisation and risk evaluation regimes they would establish.

Risk Assessments & Potential Section 6 Regulations

In January 2013, the EPA released draft risk assessments on five Work Plan chemicals. For two, trioxide (ATO) and 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB) – the risks were deemed 'negligible' or 'minimal.' For the other three – methylene chloride (or dichloromethane (DCM)), n-methylpyrrolidone (NMP), and trichloroethylene (TCE) – the assessments indicated 'a potential concern for human health under specific exposure scenarios for particular uses.'

Final risk assessments were released for all five between June 2014 and March 2015, which confirmed the initial conclusion of 'no concern' for ATO and HHCB but reiterated the initial risk concerns for MCM, NMP and TCE. Based on these, the EPA has stated that it intends to initiate rule-makings under TSCA Section 6 to regulate these chemicals.

The agency plans to determine whether the continued use of TCE in commercial degreasing operations, as a spotting agent in dry cleaning and in certain consumer products and the continued use of NMP and DCM in commercial and consumer paint and coating removers pose 'an unreasonable risk to human health and the environment' as required for a TSCA Section 6 action.

If the EPA moves forward with a Section 6 rule-making for any of these chemicals, it will be the first time it has done so in more than 25 years – and the first since its Section 6 rule banning many uses of asbestos was overturned in 1991 by a federal appeals court in *Corrosion Proof Fittings v. EPA*.

In addition to these five completed risk assessments the EPA is proceeding with assessments on a number of other chemicals as well. In April, it released a 'problem formulation' and initial assessment of 1,4-dioxane that focuses on likely risks to workers and consumers to identify exposure scenarios where additional risk analysis may be needed.

In addition, the agency has initiated risk assessments for a number of flame retardants, including a group of brominated phthalates and clusters of chlorinated phosphate esters and cyclic aliphatic bromides. An assessment of 1-bromopropane (1-BP) has also been initiated to evaluate the risks to human health from uses of 1-BP in dry-cleaning and foam glueing operations, consumer uses in aerosol solvent cleaners and spray adhesives.

The EPA is addressing the environmental impacts from the use of long- and medium chain chlorinated paraffins (C18-20 and C14-17 respectively) as metal working and compounding agents. Finally, it is evaluating the impacts on aquatic life from releases of octamethylcyclotetrasiloxane (D4). In April 2014, it signed an enforceable consent agreement with five manufacturers of D4 to conduct a one-year testing programme to gather data to be used to assess exposures and risks due to environmental releases from D4.

Significant New Use Rules

Along with the actions it is taking on its Work Plan chemicals, the EPA has been increasingly using Significant New Use Rules (SNURs) under TSCA Section 5 to place restrictions on various uses of and exposures from both existing and new chemicals. A report issued by the Government Accountability Office (GAO) in March 2013 found that the EPA's use of SNURs increased significantly from 2009 to 2012. During this period EPA issued SNURs affecting 540 chemicals, which amounted to nearly 25% of the 2,180 subject to SNURs issued since 1976, when TSCA was passed by Congress.

The EPA's use of SNURs has continued at a similar pace since the GAO report. From the beginning of 2013 to June 2015, it issued or proposed SNURs for several hundred additional chemicals. Several of the recent SNURs issued for existing chemicals have been particularly significant.

In January 2015, for example, the EPA proposed a SNUR addressing long-chain perfluoroalkyl carboxylate (LCPFAC) chemicals, which are used in cleaners, textiles, leather, paper and paints, fire-fighting foams and wire insulation. In addition to covering the manufacture, import and processing of these chemicals, the SNUR's notification requirement also would apply to LCPFAC chemicals imported as part of articles.

Under the EPA's TSCA regulations, chemical substances imported into the US as part of an article typically have not been subject to Section 5 requirements. The proposed 2015 SNUR follows up on a final SNUR issued by the EPA in December 2013 limiting the use of perfluorinated chemicals in carpets and carpet aftercare products, including making the TSCA article exemption inapplicable for LCPFAC chemical substances imported as part of carpets.

In December 2014, the EPA had issued a final SNUR for nine benzidine-based dyes, which are used in the production of textiles, paints, printing inks, paper, and pharmaceuticals. Like the SNURs for LCPFAC chemicals, this limited the import of these benzidine-based chemicals as part of an article, along with the limits it imposed on the general manufacture, import and processing of the chemicals.

In addition to these SNURs, EPA has issued or proposed SNURs limiting uses of several chemicals addressed in EPA's Action Plans, including di-n-pentyl phthalate, a short-chained chlorinated paraffin (alkanes, C12-13, chloro), 15 nonylphenols and nonylphenol ethoxylates and seven toluene diisocyanates.

Conclusion

The EPA's increased use of its existing TSCA authority since the beginning of the Obama administration already has been changing the nature of chemical regulation in the US. While the EPA's regulatory authority will be expanded if Congress passes TSCA reform legislation, its ongoing endeavours are significant in their own right and they will facilitate the agency's transition to a new regulatory regime under a modernised TSCA.

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