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Congress

TSCA

The House of Representatives has passed a bill to amend the Toxic Substances Control Act, and the Senate is expected to vote on its measure to do the same this fall. In this article, Mark Duvall of Beveridge & Diamond reviews how EPA's TSCA Work Plan may be regarded as a pilot project for implementation of TSCA reform legislation. Since 2012, the Work Plan has been the agency's primary program for identifying chemicals it intends to assess in detail. Duvall addresses a number of Work Plan topics relevant to the TSCA legislation, including prioritizing chemicals for review, scoping risk assessments, adhering to deadlines while conducting risk assessments, making risk determinations and managing the defined risk of the chemicals in question.

Implementing TSCA Legislation: Insights From EPA's TSCA Work Plan

By Mark N. Duvall

Introduction

Congress is close to enacting legislation to overhaul the Toxic Substances Control Act.[1] That legislation will likely require the EPA to prioritize chemicals, evaluate them in risk assessments and then regulate them if appropriate, all on a strict timetable. How will the EPA meet its new responsibilities? Insights into the answer are available from how the EPA has implemented its TSCA Work Plan since 2012.

For over three years, the TSCA Work Plan has been EPA's primary program for identifying chemicals that it intends to assess in detail; collecting information on those chemicals; conducting risk assessments for endpoints of concern; and then determining whether or not to initiate risk management actions. In effect, it has served as a pilot project for how the EPA may implement new TSCA authority.

This article reviews the EPA's conduct of its TSCA Work Plan as a possible forerunner of how it will implement final TSCA legislation. The article first provides a brief overview of the TSCA Work Plan and the TSCA legislation now before Congress. Then it addresses top-

[1] See Beveridge & Diamond, ''TSCA Reform Nears Enactment with Easy Passage in the House'' (June 26, 2015), http://www.bdlaw.com/assets/htmldocuments/2015-06-26%20TSCA%20Reform%20Nears%20Enactment%20with%20Easy%20Passage%20in%20the%20House.pdf.

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ics relevant to the TSCA legislation: prioritization, scope of risk assessments, time required to complete risk assessments, risk determinations and risk management. It concludes with an evaluation of the TSCA Work Plan and comments about its future.

1. Summary of the TSCA Work Plan

The TSCA Work Plan is the culmination of years of work by the EPA to address chemical issues using existing statutory authority, while calling for new authority under TSCA.[2]

Early in the Obama Administration, the EPA initiated an Enhanced Chemical Management Program. Over the next several years, the EPA took risk management action for six substances.[3] It also established action plans for 10 chemicals, then began implementing those action plans.[4] The action plan experience served as an early basis for identifying priority chemicals, but it had the drawback of being a chemical-by-chemical process, with no overarching policy to guide chemical selection. In August 2011, the EPA shifted its focus from action plans for individual chemicals to a Work Plan for Chemical Assessment. The program launched in early 2012.

The TSCA Work Plan is a process for identification and assessment of chemicals.[5] The EPA intended the TSCA Work Plan to generate a non-exhaustive list of chemicals it wishes to study further and possibly, although not necessarily, regulate.[6]

In June 2012, the EPA initially identified 83 chemicals as TSCA Work Plan chemicals and, thus, candidates for assessments.[7] In October 2014, EPA updated that list.[8] Based on new data, the EPA removed or consolidated 16 chemicals. It also added various chemicals and chemical categories based on public submissions and other data. The TSCA Work Plan chemicals list now contains 90 chemicals or chemical categories.

The EPA has completed five risk assessments of TSCA Work Plan chemicals to date and recommended or initiated risk management actions for three of them.

2. Summary of Pending TSCA Legislation

The main Senate bill is S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Environment and Public Works Committee approved an amended version of the bill on April 28, 2015.[9] The bill currently has 52 co-sponsors, 29 Republicans and 23 Democrats.[10] It is awaiting consideration by the full Senate.[11]

The House bill is H.R. 2576, the TSCA Modernization Act of 2015. The House of Representatives passed the bill on June 23, 2015, by a vote of 389 to 1.[12] It too is awaiting consideration by the Senate.[13]

The Senate bill would overhaul the major provisions of TSCA. In contrast, the House bill would mostly provide targeted solutions to key problems with the current statute. The Senate bill, at 177 pages, is much more detailed than the House bill, at 46 pages, even for common issues. The Senate bill would require the EPA to identify high- and low-priority chemicals to assess; evaluate high-priority chemicals in a safety assessment; make a safety determination based on the safety assessment about the need for regulation; and then adopt risk management rules for those chemicals found to need regulation. The House bill lacks an explicit prioritization provision. It would require the EPA to conduct a risk evaluation of selected chemicals, then regulate them if appropriate. Each bill has a preemption provision whose scope would depend on the scope of the risk assessment (safety assessment or risk evaluation).

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[2] For additional information on the TSCA Work Plan, see Beveridge & Diamond, ''TSCA Implementation at EPA: Looking Back at 2012'' (Feb. 22, 2013), http://www.bdlaw.com/assets/htmldocuments/TSCA%20Implementation%20at%20EPA%20-%20Looking%20Back.pdf, and ''TSCA Implementation at EPA: Looking Ahead'' (Feb. 22, 2013), http://www.bdlaw.com/assets/attachments/TSCA%20Implementation%20at%20EPA%20-%20Looking%20Ahead2013.pdf.

[3] EPA, ''Enhancing EPA's Chemical Management Program,'' http://www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html.

[4] EPA, ''Existing Chemical Action Plans,'' http://www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html. For a summary of the action plans for each of the 10 listed chemicals, see EPA, ''Action Plan Fact Sheet'' (Apr. 2011), http://www.epa.gov/opptintr/existingchemicals/pubs/overview.pdf.

[5] EPA, ''Identifying Chemicals for Review,'' http://www.epa.gov/oppt/existingchemicals/pubs/chemprioritizations.html.

[6] EPA, ''TSCA Work Plan for Chemical Assessments: 2014 Update'' (Oct. 2014) (hereinafter ''October 2014 Work Plan Chemicals List''), http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Work_Plan_Chemicals_2014_Update-final.pdf.

[7] EPA, ''TSCA Work Plan Chemicals'' (June 2012), http://www.epa.gov/oppt/existingchemicals/pubs/Work_Plan_Chemicals_Web_Final.pdf.

[8] EPA, October 2014 Work Plan Chemicals List.

[9] The text of S. 697 as of June 17, 2015, is available at https://www.congress.gov/114/bills/s697/BILLS-114s697rs.pdf.

[10] See S. 697 – Frank R. Lautenberg Chemical Safety for the 21st Century, https://www.congress.gov/bill/114th-congress/senate-bill/697/cosponsors.

[11] See Beveridge & Diamond, ''Amended Udall-Vitter TSCA Reform Bill Reaches Senate Floor'' (Apr. 29, 2015), http://www.bdlaw.com/assets/htmldocuments/2015-04-29%20Amended%20Udall-Vitter%20TSCA%20Reform%20Bill%20Reaches%20Senate%20Floor.pdf.

[12] The text of H.R. 2576 as of July 8, 2015 is available at https://www.congress.gov/114/bills/hr2576/BILLS-114hr2576pcs.pdf.

[13] See Beveridge & Diamond, ''TSCA Reforms Near Enactment with Easy Passage in the House'' (June 26, 2015), http://www.bdlaw.com/assets/htmldocuments/2015-06-26%20TSCA%20Reform%20Nears%20Enactment%20with%20Easy%20Passage%20in%20the%20House.pdf.

3. Prioritization of Chemicals to Evaluate

The Senate bill has a detailed prioritization provision based in part on the TSCA Work Plan. The House bill does not have any prioritization provision, but the House Report anticipates that the EPA will evaluate TSCA Work Plan chemicals in the early years of implementation of the legislation. Thus, it is likely that the EPA will adapt the TSCA Work Plan prioritization methodology to select chemicals to evaluate under final TSCA legislation. Accordingly, it may be helpful to review the methodology in some detail.

a. The Senate Bill

The Senate bill would require the EPA to ''establish, by rule, a risk-based screening process and explicit criteria for identifying existing chemical substances'' that are high or low priorities for a safety assessment.[14] The EPA would have to publish an initial list of high-priority substances, which would have to include at least 10 high- and 10 low-priority substances. At least five of the high-priority substances would have to come from the October 2014 update to the list of TSCA Work Plan chemicals and any future updates. At least 50 percent of subsequent additions to the list of high-priority chemicals also would have to come from the October 2014 TSCA Work Plan list and its updates ''until all Work Plan chemicals have been designated under this subsection.''[15]

The Senate Report directs the EPA to ''rely on existing processes, such as those established under the Agency's TSCA Work Plan Chemical program, to manage the process [of systematically assessing and determining the safety of priority chemicals] as new policies and procedures are developed.''[16] The EPA would be required to draw ''no less than 50%'' of its initial list of high-priority chemicals from the Work Plan Chemical list because ''EPA has already prioritized these chemicals for review; the Committee does not intend that EPA start work anew on these substances.''[17]

Additionally, the Senate bill would require the EPA to ''give preference to chemical substances scored as high for persistence and bioaccumulation in'' the Work Plan and its updates.[18]

New Section 4A also would provide for additional priorities for EPA's safety assessments and determinations. The prioritization process would have to allow manufacturers or processors of substances not designated as high-priority or not being considered for prioritization to request that EPA ''designate the substance as an additional priority for a safety assessment and safety determination'' so long as the requester agrees to pay 100 percent of the cost of review (50 percent if the requested chemical is a TSCA Work Plan chemical).[19] In considering such a request, the EPA would be limited in its discretion: ''[I]f a sufficient number of additional priority requests'' are made, at least 25 percent of the chemicals designated for analysis must come from the requests but no more than 30 percent may come from the list, effectively keeping at least 70 percent of the list EPA-listed chemicals.[20] As chemicals on the Work Plan list have effectively already been ''chosen'' by the EPA as chemicals to consider as high-priority substances, requests made for chemicals identified in the October 2014 Work Plan would not be subject to the 30 percent cap.[21] Chemicals requested to be reviewed from the list would be approved at the EPA's discretion, and ''requests for additional Work Plan chemicals under this subsection shall be considered high-priority chemicals. . . .''[22] Work Plan chemicals that become high-priority substances through this nomination process would trigger preemption (the ''high-priority pause''), but would not have to be replaced through the repopulation provision for the list of high-priority substances.[23] While the ''EPA has full discretion to approve or deny these petitions[,] the Committee intends for EPA to utilize this provision, resources allowing, to conduct safety assessments and determinations of all Work Plan chemicals as quickly as possible.''[24]

b. The House Bill

The House bill has no counterpart to the Senate bill's prioritization provision. Nevertheless, the House Report says that the ''Committee expects that many, if not all, of the Agency's selections for Agency initiated risk evaluation in the first year after enactment will come from the Work Plan and that risk evaluations for Work Plan chemicals will be completed in the first years.''[25]

c. The TSCA Work Plan

In 2012, EPA selected seven chemicals to be the first to receive risk assessments under the TSCA Work Plans: antimony and antimony compounds; 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB); long-chain chlorinated paraffins; medium-chain chlorinated paraffins; n-methyl-2-pyrrolidone (NMP); methylene chloride; and trichloroethylene (TCE).

The EPA subsequently selected an additional seven TSCA Work Plan chemicals to review: 1-bromopropane (1-BP); 1,4-dioxane; 2-ethylhexyl 2,3,4,5-tetrabromobenzoate (TBB); bis(2-ethylhexyl) 3,4,5,6-tetrabromophthalate (TBPH); hexabromocyclododecane (HBCD); octamethylcyclotetrasiloxane (D4); and tris(2-chloroethyl)phosphate (TCEP).

The EPA released the methodology used to identify these chemicals in February 2012,[26] with an update in October 2014.[27] Generally, the EPA categorizes chemicals by use based on various databases and then by a composite score of hazard, exposure and persistence and bioaccumulation.

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[14] S. 697, § 6 (proposed § 4A(a)(1)).

[15] S. 697, § 6 (proposed § 4A(a)(2)(B)(ii)).

[16] Senate Report 114-67, The Frank R. Lautenberg Chemical Safety for the 21st Century Act, at 9 (June 18, 2015), https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf.

[17] Senate Report 114-67, at 12.

[18] S. 697, § 6 (proposed § 4A(a)(2)(B)(iii)).

[19] S. 697, § 6 (proposed § 4A(c)(1)(A)(i)). See also S. Rep. No. 114-67 at 13.

[20] S. 697, § 6 (proposed § 4A(c)(2)(A)).

[21] S. 697, § 6 (proposed § 4A(c)(3)(A)-(B)).

[22] S. 697, § 6 (proposed § 4A(c)(3)(B)).

[23] S. 697, § 6 (proposed § 4A(c)(3)(A)-(B)).

[24] Senate Report 114-67 at 13.

[25] House Report 114-176, TSCA Modernization Act of 2015, at 24, https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.

[26] EPA, TSCA Work Plan Chemicals: Methods Document (February 2012), http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf.

[27] EPA, October 2014 Work Plan Chemicals List.

Step 1: First, the EPA identifies chemicals to consider. It focuses on chemicals that pose a significant potential for exposure to humans and/or the environment. The EPA uses a comment period, which includes a discussion forum, webinar and stakeholder meeting, to refine its criteria for evaluation. The EPA identifies chemicals and chemical groups meeting one or more of the following factors:

- Chemicals identified as potentially of concern for children's health.
- Chemicals identified as persistent, bioaccumulative and toxic.
- Chemicals identified as probably or known carcinogens.
- Chemicals used in children's products.
- Chemicals used in consumer products.
- Chemicals detected in biomonitoring programs.
- Chemicals known to exhibit neurotoxicity.

The EPA relies on a series of databases to find chemicals meeting the above criteria. The EPA then excludes from the list chemicals meeting any of the following criteria:

- Pesticides regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).
- Drug hormone and pharmacological chemicals regulated under the Federal Food, Drug and Cosmetic Act (FFDCA).
- Radioactive materials regulated under the Atomic Energy Act (AEA); process streams and byproducts not commercially produced.
- Polymers.
- Common gases.
- Naturally occurring chemicals and combustion products.
- Common oils or fats and simple plant extracts.
- Explosive, pyrophoric or extremely reactive or corrosive chemicals.
- Chemicals already the subject of action plans (some action plan chemicals were later added to the list of TSCA Work Plan chemicals).
- Metals identified as toxic to the environment but not to people.

The EPA applies these exclusions and then proceeds to step 2.[28]

Step 2: The EPA scores the remaining chemicals on the basis of general hazard, exposure and persistence and bioaccumulation. For chemicals with sufficient data to score in each of the three categories, the EPA generates a composite score and ranks the chemicals into three categories: high, moderate or low risk. Those chemicals that lack sufficient data to score in each of the three categories are seen as potential TSCA Work Plan chemicals.

From step 2, the EPA identifies ''high'' ranking chemicals meriting assessment. TSCA Work Plan chemicals are listed in a spreadsheet online. The final documentation includes a chemical name, the date the chemical was added, the specific hazard criteria met and the hazard score, the specific exposure criteria met and the exposure score, the persistence and bioaccumulation criteria met and associated score, the chemical's evaluated use, and the Chemical Abstract Service registry number.

This methodology yields considerably more chemicals than the EPA can address in the short term. It has used a variety of subjective considerations to select its priority chemicals. It has identified those considerations,[29] but not how it applied them to select particular chemicals.

This methodology has received little public criticism. Given the endorsement of this methodology by the Senate bill and the House Report, the EPA is likely to use it as the basis for its prioritization process under final TSCA legislation.

4. Scope of the Risk Assessment

Under TSCA legislation, the EPA would be required to conduct risk assessments of priority chemicals. Under the TSCA Work Plan, the EPA has developed a process for conducting risk assessments that may be the basis for future risk assessments under final TSCA legislation.

a. The Senate Bill

The Senate bill would not specify the scope of the safety assessment other than to indicate that sensitive

[28] EPA, TSCA Work Plan Chemicals: Methods Document.

[29] The TSCA Work Plan: Methods Document explained: ''In identifying a smaller set of chemicals for work in any given year, EPA considers a number of factors, including:

- Whether the chemical was identified as a ''High'' ranking chemical.
- Whether the chemical reflects more than one of the factors identified in Step 1 (for example, chemicals that were identified as a potential concern for children's health and also were persistent, bioaccumulative, and toxic) and whether each of the factors was covered by the set of chemicals. These factors included health and environmental hazards, children's health, use in consumer products and dispersive uses, persistence and bioaccumulation, and detection in biomonitoring and environmental monitoring.
- Whether certain chemicals, or groups of chemicals, would benefit from some preliminary work to assure that risk assessments are targeted and scoped appropriately, and therefore would best be addressed in an out year.
- Whether certain chemicals, or groups of chemicals, have previously been assessed and addressed by the Agency, so that risk assessment in later years may be more appropriate than in the earlier years of the work plan.
- Agency work load considerations, including scope and timing of work needed on specific chemicals, and existing commitments for assessment.''

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subpopulations should be considered. It would require the EPA to ''define and publish the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider.''[30]

The scope of the safety assessment would in turn determine the scope of any preemption. Preemption would apply only to ''the uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance.''[31] Any preemption of new state requirements based on EPA's initiation of a safety assessment would begin ''on the date on which the Administrator defines the scope of a safety assessment and safety determination.''[32]

b. The House Bill

Unlike the Senate bill, the House bill would mandate a broad risk assessment. It would direct the EPA to ''integrate and assess information on hazards and exposures for all of the intended 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 subpopulations.''[33] Thus, the EPA would have to consider ''all'' conditions of use.

As with the Senate bill, the scope of preemption would be limited to the scope of the risk assessment. Preemption would apply only to a state ''requirement that applies to such chemical substance under the intended conditions of use considered by the Administrator in the risk evaluation under section 6(b).''[34]

c. The TSCA Work Plan

The scope of the risk assessments to date under the TSCA Work Plan has been fairly narrow, reflecting data limitations and risks of particular concern:

■ For the category of antimony and antimony compounds, EPA focused solely on antimony trioxide (ATO), a synergist in halogenated flame retardants in textiles and plastics, because it constitutes 80 percent of antimony consumption in the U.S. The EPA limited review to the effects of ATO on biological organisms because of the available ecotoxicity information and the reported industrial releases.[35]

■ The EPA assessed HHCB, a polycyclic musk fragrance ingredient, only with respect to environmental risks in aquatic environments from direct exposure to consumer and commercial products containing HHCB. The EPA did not consider human health concerns in the risk assessment because of available health data and a European Union study which concluded that no further study was necessary.[36]

■ The risk assessment for NMP, a solvent, focused on occupational and consumer paint stripping uses because of high content in products and high potential exposure to workers and consumers. The EPA did not consider environmental effects because of NMP's low ecological hazard, low persistence and low bioaccumulation.[37]

■ The EPA limited the scope of its risk assessment of methylene chloride, a solvent with industrial, commercial and consumer applications, to inhalation exposures from paint strippers. It did so in part because it lacked both data and methodology for evaluating dermal exposures. It also did not consider ecological risks because environmental releases were not considered heavy.[38]

■ The risk assessment for TCE focused on its commercial use as a solvent degreaser and spotting agent in dry cleaning, and its consumer use as a solvent degreaser and spray-applied coat for arts and crafts. The EPA excluded environmental effects because the uses considered were unlikely to result in substantial environmental releases and because the EPA's other offices were addressing TCE found in groundwater and soils.[39]

The EPA has begun to formalize its problem definition process for its TSCA Work Plan risk assessments. Problem definitions could serve as the scope of the risk assessment for purposes of final TSCA legislation. The first chemical for which the EPA has released a problem formulation and initial assessment was 1,4-dioxane in April 2015.[40] Since then, the EPA has issued additional problem formulations for four clusters of flame retardants.[41]

Problem formulation and initial assessment are ''a first step'' in the chemical evaluation process. That step helps to determine if ''available data and current assessment approaches and tools will support the assessment.'' While 1,4-dioxane is the first for which such a document was published, ''EPA will be publishing a problem formulation and initial assessment for each

[30] S. 697, § 8(3) (proposed § 6(a)(2)).
[31] Id. (proposed § 18(c)(2)).
[32] Id. (proposed § 18(b)(1)).
[33] H.R. 2576, § 4(b) (proposed § 6(b)(3)(A)(i)).
[34] Id., § 7(a)(2) (proposed § 18(a)(2)(B)).
[35] EPA, TSCA Work Plan Chemical Risk Assessment Antimony Trioxide (Aug. 2014), http://www.epa.gov/oppt/existingchemicals/pubs/ATO%20RA_(8-28-14)_FINAL.PDF.
[36] EPA, TSCA Work Plan Chemical Risk Assessment HHCB (Aug. 2014), http://www.epa.gov/oppt/existingchemicals/pubs/HHCB%20WP%20RA%20FINAL%2008_27_14.pdf.
[37] EPA, TSCA Work Plan Chemical Risk Assessment N-Methylpyrrolidone: Paint Stripper Use (Mar. 2015), http://www.epa.gov/oppt/existingchemicals/pubs/nmp_ra_3_23_15_final.pdf.
[38] EPA, TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use (Aug. 2014), http://www.epa.gov/oppt/existingchemicals/pubs/DCM_OPPTWorkplanRA_final.pdf.
[39] EPA, TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses (June 2014), http://www.epa.gov/oppt/existingchemicals/pubs/TCE_OPPTWorkplanChemRA_FINAL_062414.pdf.
[40] EPA, TSCA Work Plan Chemical Problem Formulation and Initial Assessment 1,4-Dioxane (Apr. 2015), http://www.epa.gov/oppt/existingchemicals/pubs/14-Dioxane_final.pdf.
[41] An announcement about the problem formulations appeared at 80 Fed. Reg. 49,997 (Aug. 18, 2015). The documents are available at http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html#esters. The clusters are chlorinated phosphate esters, cyclic aliphatic bromides, tetrabromobisphenol A and brominated phthalates.

TSCA Work Plan Chemical assessment to facilitate public and stakeholder comment and input prior to conducting further risk analysis.''[42] The EPA opened a public docket upon issuing the problem formulation to increase transparency and stakeholder involvement in the evaluation process.

The relatively narrow scope of the risk assessments to date might suggest that the EPA would similarly focus narrowly under final TSCA legislation. However, the NMP risk assessment indicates otherwise, at least in some cases. The EPA limited the focus of that risk assessment to a sensitive subpopulation, explaining:

> The quantification of exposures focused on pregnant women and women of childbearing age who may become pregnant, because the most sensitive health effects selected for use in the risk assessment affect the fetus. EPA/OPPT assumed that exposures that do not result in unacceptable risks for these specific lifestages would also be protective of others, including children, for other adverse outcomes.

In other words, the EPA used a ''sentinel'' approach. This involves identification of exposures of greatest concern. If found not to merit regulation, the approach suggests that lower-risk exposures also do not merit regulation.

5. Timing to Complete a Risk Assessment

a. Senate, House Bills

Both bills would give the EPA three years to complete a risk assessment for a priority chemical that it identifies, subject to a limited extension.

The Senate bill would allow three years to complete a safety assessment and safety determination for a chemical from the date of designation of the chemical as a high priority. The EPA then would have two years to complete a risk management rulemaking from the date of publication of the safety assessment and safety determination. Those dates could be extended, but for no more than an aggregate of two years.[43]

Similarly, the House bill would allow three years to complete a risk evaluation for a chemical selected by the EPA, two years for a chemical nominated by a manufacturer. The risk management rule would be due two years later. All deadlines could be extended, subject to an aggregate of two years.[44]

b. The TSCA Work Plan

The EPA has met the three-year deadline of the Senate and House bills for the risk assessments it has completed to date, including time for public comment and peer review:

■ ATO: the EPA identified antimony and antimony compounds for review in March 2012.[45] It announced availability of the draft risk assessment for comment in January 2013[46] and held three peer review meetings later that year.[47] The peer review panel completed its review in December 2013.[48] The EPA issued the final risk assessment in August 2014, or 29 months from time of selection.

■ HHCB: the EPA initiated the risk assessment in March 2012,[49] and announced availability of the draft risk assessment for comment in January 2013.[50] It held three peer review meetings later that year.[51] The peer review panel completed its review in January 2014.[52] The final risk assessment issued in August 2014, or 29 months after beginning the review.

■ NMP: the EPA began its review in March 2012. It announced availability of the draft risk assessment in January 2013,[53] and three peer review meetings later that year.[54] The final risk assessment was released in March 2015, or 36 months after initiation.

■ Methylene chloride: The risk assessment began in March 2012. EPA announced availability of the draft risk assessment in January 2013,[55] and held three peer review meetings later that year.[56] The final risk assessment was released in August 2014, or 29 months after initiation.

■ TCE: the EPA began its review of TCE in March 2012.[57] It announced availability of the draft risk assessment in January 2013.[58] It held three peer review meetings later that year.[59] The final risk assessment was released in June 2014, or 27 months after initiation.

On the other hand, the EPA still has not issued draft risk assessments for two of the seven initial risk assessment candidates announced in February 2012. The missing risk assessments are those for long-chain and medium-chain chlorinated paraffins. The EPA has apparently found that it needed additional testing to complete the risk assessments. The EPA reportedly conducted that testing itself or through a contractor, rather than having manufacturers conduct the testing.

In selecting the initial seven chemicals or chemical categories for risk assessments under the TSCA Work Plan, the EPA explained that it considered ''whether certain chemicals, or groups of chemicals, would benefit from some preliminary work to assure that risk assessments are targeted and scoped appropriately, and

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[42] 80 Fed. Reg. 23,545 (Apr. 28, 2015).
[43] S. 697, § 8(3) (proposed § 6(a)).
[44] H.R. 2576, § 4(b) (proposed § 6(b)(5)).
[45] EPA, TSCA Work Plan Chemical Risk Assessment Antimony Trioxide (Aug. 2014).
[46] 78 Fed. Reg. 1856 (Jan. 9, 2013).
[47] See 78 Fed. Reg. 59,679 (Sept. 27, 2013); 78 Fed. Reg. 67,141 (Nov. 8, 2013).
[48] EPA, OPPT Antimony Trioxide (ATO) Draft Risk Assessment Draft Comments of Seven-Member Peer Review Panel (Dec. 12, 2013), http://www.epa.gov/oppt/existingchemicals/pubs/ATO_Consolidated_Peer_Review_Comments_December_13_2013.pdf.
[49] EPA, TSCA Work Plan Chemical Risk Assessment HHCB (Aug. 2014).
[50] 78 Fed. Reg. 1856 (Jan. 9, 2013).
[51] See 78 Fed. Reg. 59,679 (Sept. 27, 2013); 78 Fed. Reg. 67,142 (Nov. 8, 2013).
[52] EPA, ''HHCB Draft Risk Assessment Draft Comments of Seven-Member Peer Review Panel'' (Jan. 27, 2014), http://www.epa.gov/oppt/existingchemicals/pubs/HHCB_Consolidated_Peer_Review_Comments_January-27_2014.pdf.
[53] 79 Fed. Reg. 1856 (Jan. 9, 2013).
[54] 79 Fed. Reg. 52,525 (Aug. 23, 2013).
[55] 79 Fed. Reg. 1856 (Jan. 9, 2013).
[56] 79 Fed. Reg. 52,525 (Aug. 23, 2013).
[57] EPA, TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses (June 2014).
[58] 79 Fed. Reg. 1856 (Jan. 9, 2013).
[59] 79 Fed. Reg. 52,525 (Aug. 23, 2013).

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therefore would best be addressed in an out year.''[60] With long- and medium-chain chlorinated paraffins, the EPA would probably have done better to wait to designate them as priority chemicals until necessary testing was completed. The Senate bill would allow the EPA to require testing by manufacturers and processors for the purpose of prioritization[61] and for conducting a safety assessment or safety determination. Similarly, the House bill would authorize testing for purposes of conducting a risk evaluation.[62] The EPA recently released a data needs assessment for the brominated phthalate cluster of flame retardants ''to guide the collection of additional data and information to fill the critical data gaps and reduce uncertainties identified during problem formulation.'' [63] This approach can be seen as stopping short of designating this cluster as a high priority and thus would not start the three-year clock under final TSCA legislation.

6. Risk Determinations

The aim of a risk assessment is to describe the risks posed by a chemical and then evaluate those risks. The Senate bill would call for the EPA to make a safety determination about whether the chemical evaluated does or does not meet a safety standard based on unreasonable risk.[64] The House bill would require the EPA to determine whether or not a chemical substance presents or will present, in the absence of additional risk management requirements, an unreasonable risk of injury to health or the environment.[65] In the five TSCA Work Plan risk assessments completed to date, the EPA has made risk determinations. It found that three of the five chemicals evaluated posed risks meriting regulation:

- ATO: Though its results were uncertain due to the limitations of available information, the EPA concluded that ATO poses a low ecological risk.[66]

- HHCB: the EPA found exposures generally to be well below risk levels. It concluded that use of HHCB poses little danger of direct exposure to aquatic and sediment-dwelling organisms in concentrations of concern.[67]

- NMP: The assessment identified risks from acute exposures of four hours per day when gloves were not used. It also found risks from exposures of greater than four hours per day; these risks were not mitigated by personal protective equipment such as respirators or gloves.[68]

- Methylene chloride: The risk assessment found cancer risk concerns and short- and long-term noncancer risks for workers, but it only found short-term noncancer risks for residential users.

- TCE: The risk assessment concluded that TCE exposure of the types considered results in cancer risks and short- and long-term noncancer risks for workers in degreasing and dry cleaning facilities, and short-term noncancer risks for consumers.[69]

The EPA did not frame these risk determinations in terms of unreasonable risk. Nevertheless, these risk assessments support the idea that the EPA will be able to conduct risk assessments and reach risk-based conclusions after doing so.

7. Risk Management

The biggest challenge facing the EPA in the TSCA Work Plan has been how to regulate chemicals found to pose risks of substantial concern. The EPA has authority under Section 5 of TSCA to issue significant new use rules (SNURs) for chemicals whose uses are not ongoing (and thus are new). However, it feels that it lacks an effective mechanism for regulating under Section 6 chemicals whose uses are ongoing.[70] Final TSCA legislation should make that challenge less daunting.

Notwithstanding this challenge, the EPA has announced plans to initiate rulemaking under Section 5 and/or Section 6 for three Work Plan chemicals:

- The EPA intends to publish a notice of proposed rulemaking under Section 6 to regulate NMP and methylene chloride jointly. The rulemaking will consider whether use of the chemicals ''in commercial and consumer paint and varnish strippers pose an unreasonable risk to human health and the environment.''[71]

- The EPA has announced plans to regulate TCE under both Sections 5 and 6.

- EPA issued the proposed SNUR on July 30, 2015 with exceptions for ongoing uses in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray.[72]

- The EPA intends to publish a notice of proposed rulemaking under Section 6 for TCE. That rulemaking will consider whether ''the continued use of TCE in some commercial degreasing uses, as a spotting agent in dry cleaning, and in certain consumer products would pose an unreasonable risk to human health and the environment.'' In other words, the EPA would fill the gaps left in the SNUR due to ongoing uses by adopting a Section 6 rule applicable to those uses.

According to the spring 2015 Regulatory Agenda, the EPA plans to issue notices of proposed rulemaking for these Section 6 rules in January 2016, one for NMP and

[60] EPA, TSCA Work Plan Chemicals: Methods Document.
[61] S. 697, § 5(5) (proposed § 4(a)(1)(A), 4(a)(2)).
[62] H.R. 2576, § 3(1)(C) (proposed § 4(a)(1)(C)).
[63] EPA, TSCA Work Plan Chemical Problem Formulation and Data Needs Assessment: Brominated Phthalates Cluster Flame Retardants (Aug. 2015), at 8, http://www.epa.gov/oppt/existingchemicals/pubs/Brominated_Phthalates_Cluster_Data_Needs_Assessment.pdf
[64] S. 697, § 8(1) (proposed § 6(c)).
[65] H.R. 2576, § 4(b) (proposed § 6(b)(1)).
[66] EPA, TSCA Work Plan Chemical Risk Assessment Antimony Trioxide (Aug. 2014)
[67] EPA, TSCA Work Plan Chemical Risk Assessment HHCB (Aug. 2014).
[68] EPA, TSCA Work Plan Chemical Risk Assessment N-Methylpyrrolidone: Paint Stripper Use (Mar. 2015).
[69] EPA, TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses (June 2014).
[70] The EPA has not initiated a Section 6 rulemaking in 24 years, since a court invalidated its Section 6 rule banning most uses of asbestos in 1991. The EPA subsequently concluded that it effectively cannot exercise its authority under Section 6 due to that section's statutory demands, such as selection of the least burdensome remedy.
[71] EPA Regulatory Agenda Spring 2015 (May 21, 2015), http://op.bna.com/env.nsf/r?Open=smiy-9ztkdm.
[72] Proposed 40 C.F.R. § 721.10851, 80 Fed. Reg. 47,441 (Aug. 27, 2015).

methylene chloride, and another for TCE.[73] Thus, the proposals may appear after final TSCA legislation gives the EPA new and more flexible Section 6 authority.

In addition to rulemaking, the EPA can encourage voluntary risk reduction actions. The EPA announced a voluntary action with respect to TCE on July 30, 2015, as a result of the TCE risk assessment.[74]

8. Evaluation of the TSCA Work Plan

As a pilot project for implementation of an amended TSCA, the TSCA Work Plan has been a success. It has helped the EPA understand what works and what should be changed with respect to the issues addressed above.

The methodology for selecting TSCA Work Plan chemicals is clearly more well-reasoned than whatever process the EPA used to select the action plan chemicals. That methodology is transparent and considers a variety of relevant factors. The EPA already has modified it through experience. Both the methodology and the current list of 90 TSCA Work Plan Chemicals have achieved recognition in the Senate and House bills and their respective committee reports.

The scoping process for risk assessments has evolved during the life of the TSCA Work Plan. The five risk assessments completed to date include a discussion of the scope and the reasons for that scope, but those statements came late in the process. With the 1,4-dioxane problem definitions, the EPA has made the process more transparent and, possibly, more thorough. It has also provided opportunity for public input on the scope, which can be valuable. That is the process the EPA plans to use with future risk assessments.

The EPA has used a process for conducting risk assessments which allows for both public comment on drafts and peer review, while still meeting the three-year window allocated in the Senate and House bills. The experience with long- and medium-chain chlorinated paraffins is the exception. That experience suggests the need in the scoping stage to consider data needs and data gaps before identifying a chemical as a priority for a risk assessment. By doing so, the EPA can proceed to fill important data gaps, either by requiring others to conduct testing or by doing the testing itself.

Unlike Integrated Risk Information System (IRIS) evaluations, which look only at hazard, the EPA's TSCA Work Plan risk assessments have considered exposure and use. The EPA has been able to identify risks of greater and lesser concern. Thus, under final TSCA legislation it should be able to make determinations of whether or not a chemical will present an unreasonable risk under the intended conditions of use (or whatever the final language provides).

The timing for risk management rulemaking remains a significant question under the TSCA Work Plan and under final TSCA legislation. The EPA has predicted it will issue two proposed Section 6 rules in January 2016. If the EPA meets that date, the proposal for NMP and methylene chloride will come 10 months after the final risk assessment for NMP and 14 months after the final risk assessment for methylene chloride. The TCE proposed Section 6 rule would come 18 months after the final risk assessment for TCE. The EPA would then take comments and proceed to adopt final rules, a process likely to take several years. The House bill would only allocate 12 months for publication of a proposed rule and another 12 months for the final rule. The Senate bill would allocate 24 months from the final risk assessment to adopt a final rule. Both bills would allow extensions up to two years.

There is reason for concern that the EPA will meet those deadlines even with taking the full two-year extension in each case. A cautionary example is the EPA's formaldehyde rulemaking. In July 2010, in the Formaldehyde Standards for Composite Wood Products Act, Congress directed the EPA to implement nationally essentially the California Air Resources Board emissions requirements.[75] In other words, Congress dictated most of the content of the rule. The final rule was to be published ''not later than January 1, 2013,'' two and a half years later. EPA published two proposed rules in June 2013 (three years after enactment and six months after the final rules were due).[76] It predicts that it will publish the final rules in November 2015 (five years and four months after enactment, and nearly three years after the statutory deadline).[77]

9. Future of the TSCA Work Plan

Once Congress enacts and the president signs final TSCA legislation, the EPA is likely to end the TSCA Work Plan as such. Thereafter, it will begin work to develop the procedures, policies, guidance and rules called for by that legislation. Nevertheless, the TSCA Work Plan experience is likely to give the EPA a head start in implementing an amended TSCA.

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[73] EPA Regulatory Agenda Spring 2015 (May 21, 2015) at 142, 144, http://op.bna.com/env.nsf/r?Open=smiy-9ztkf5.

[74] The EPA reached an agreement with PLZ Aeroscience Corp. to voluntarily phase out by Sept. 1 its use of TCE in the only aerosol arts and crafts spray fixative product on the market. The EPA's news release attributed the agreement to the TSCA Work Plan: ''TCE is an example of how EPA's assessment of existing chemicals can lead to real results that protect health and the environment. After identifying health risks associated with a number of TCE uses in its June 2014 Work Plan Chemical Risk Assessment conducted under the Toxic Substances Control Act (TSCA), EPA worked with the manufacturers of TCE on possible voluntary efforts to reduce exposure.'' See http://yosemite.epa.gov/opa/admpress.nsf/0/A4964AD93874985C85257E92005EE07F.

[75] Pub. L 111-199 (July 7, 2010), adding Title VI of TSCA. The January 1, 2013 deadline appears in TSCA § 603(d)(1).

[76] 78 Fed. Reg. 34,796 (June 10, 2013) (third-party certification framework); 78 Fed. Reg. 34,820 (June 10, 2013) (formaldehyde emissions standards).

[77] EPA Spring 2015 Regulatory Agenda (May 21, 2015) at 147, 151.

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