2021 Annual Plan for Chemical Risk Evaluations Under TSCA

December 21, 2021

Background

The Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act") (Public Law [P.L.114-182]), signed by President Obama on June 22, 2016, substantially amended the Toxic Substances Control Act (TSCA) to enhance public health, chemical safety, and interstate commerce by providing the U.S. Environmental Protection Agency (EPA) with significant new authorities and obligations. TSCA section 26(n) requires:

At the beginning of each calendar year, the Administrator shall publish an annual plan that—
(A) identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion;

(B) describes the status of each risk evaluation that has been initiated but not yet completed; and (C) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

This plan fulfills the requirement of TSCA section 26(n) for 2021.²

10 EPA-Initiated Risk Evaluations Commenced in 2016

TSCA section 6(b)(2)(A) required the EPA to ensure that risk evaluations were initiated for 10 chemical substances within 180 days of enactment of the Lautenberg Act. TSCA required that the first 10 chemicals be drawn from the 90 chemicals on the EPA's 2014 Update to the TSCA Work Plan.³ TSCA further requires that for each High-Priority Substance (HPS) risk evaluation completed, EPA must begin a new HPS risk evaluation. By the end of calendar year 2019, the EPA was required to have at least 20 HPS risk evaluations underway at any given time. At least half of all EPA-initiated risk evaluations must be drawn from the 2014 Update to the TSCA Work Plan until that list has been exhausted. The EPA released proposed designations of 20 HPS in August 2019 and finalized the designations in December 2019. More information on those risk evaluations is provided below.

On November 29, 2016, the EPA announced the first 10 chemicals that would undergo risk evaluation under the law.⁴ The list was published in the *Federal Register* on December 19, 2016, and included the following chemical substances: 1,4-Dioxane, Methylene Chloride, 1-Bromopropane (1-BP), N-Methylpyrrolidone (NMP), Chrysotile Asbestos, Pigment Violet 29 (PV29), Carbon Tetrachloride, Trichloroethylene (TCE), Cyclic Aliphatic Bromide Cluster (HBCD), and Perchloroethylene (PCE).⁵ From the date of publication, the EPA had three years, with a possible six-month extension, to complete

¹ See https://www.epa.gov/sites/default/files/2016-06/documents/bills-114hr2576eah.pdf.

² Previous annual plans are available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/2020-annual-report-risk-evaluations.

³ See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-assessments-2014-update.

⁴ See https://19january2017snapshot.epa.gov/newsreleases/epa-names-first-chemicals-review-under-new-tsca-legislation_.html and https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca.

⁵ See https://www.federalregister.gov/documents/2016/12/19/2016-30468/designation-of-ten-chemical-substances-for-initial-risk-evaluations-under-the-toxic-substances and https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca.

those risk evaluations. The risk evaluations were completed between June 2020 and January 2021, with all but one missing the statutory deadline.⁶

During the risk evaluation for asbestos, the EPA decided to separate evaluation of legacy uses of asbestos from the evaluation of Chrysotile Asbestos. As a result of the November 14, 2019, decision of the U.S. Court of Appeals for the Ninth Circuit in *Safer Chemicals Healthy Families v. EPA*, the agency will also evaluate legacy asbestos uses and associated disposals of asbestos in a supplemental effort that will be the focus of the second part of the risk evaluation for asbestos. Legacy uses and associated disposals of asbestos are conditions of use for which manufacture (including import), processing, and distribution in commerce no longer occur, but for which use and disposal are still known, intended, or reasonably foreseen to occur (e.g., asbestos in older buildings). Although still considered part of the 2016 first 10 chemicals, legacy asbestos is being assessed on a schedule in parallel with the 2019 HPS assessments.

The EPA recognizes that special attention is often needed to ensure technical consideration of environmental risk factors associated with Tribal and environmental justice populations. From fall 2020 through summer 2021, the EPA conducted Tribal consultation and environmental justice consultations to better understand unique exposure pathways or end points of concern and obtain data sources that could improve the analysis of potential risk. These engagements included discussion of the development of proposed actions under TSCA section 6(a) to address the unreasonable risks that the EPA determined were presented by these chemical substances under their conditions of use.

On June 30, 2021, the EPA announced that it would take a number of actions affecting some of the first 10 chemical risk evaluations to ensure that the risk management actions that follow are sufficiently protective and scientifically and legally defensible. First, the EPA intends to re-open and update the 1,4dioxane risk evaluation to consider whether to include additional exposure pathways, such as drinking water and ambient air, and conditions of use for which 1,4-dioxane is generated as a byproduct. Second, for six of the first 10 chemicals (methylene chloride, trichloroethylene, carbon tetrachloride, perchloroethylene, NMP, and 1-bromopropane), the EPA plans to further examine whether the previous Administration's policy decision to exclude air and drinking water exposure pathways from the risk evaluations will lead to a failure to identify and protect potentially exposed and susceptible subpopulations as the law requires, with a particular focus on fenceline communities. If this approach vields information that there is no unreasonable risk to these communities from a substance, the EPA intends to move forward to propose risk management rulemakings. If the agency finds there may be unreasonable risk to such communities that cannot be addressed through the risk management approaches the agency is already considering using the completed risk evaluation, the EPA will conduct a more comprehensive exposure assessment of fenceline communities and supplement the risk evaluation for that chemical with the new information.

Third, the EPA is revisiting the assumption that personal protective equipment (PPE) is always used in occupational settings when making risk determinations for a chemical. Instead, the agency plans to consider information on use of PPE, or other ways industry protects its workers, as a potential way to address unreasonable risk during the risk management process. This shift could change some of the unreasonable risk determinations for some conditions of use of the first 10 chemicals for which "no unreasonable risk" findings were made based on the use of PPE. Specifically, this shift could impact conclusions about risk for some conditions of use for methylene chloride, 1-bromopropane, HBCD, NMP, perchloroethylene, and 1,4-dioxane. Fourth, the EPA intends to reissue the risk determinations to include a whole chemical risk determination for the first 10 chemicals that will replace condition of use by

⁶ See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca

⁷ See https://law.justia.com/cases/federal/appellate-courts/ca9/17-72260/17-72260-2019-11-14.html.

⁸ See https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

condition of use risk determinations with one finding per chemical. The EPA intends to withdraw the previously issued orders for those conditions of use for which no unreasonable risk was found. The agency intends to seek public comment on this approach.

20 EPA-Initiated Risk Evaluations Commenced in 2019

In August 2019, the EPA released proposed designations of 20 high-priority chemicals. In December 2019, the EPA finalized the designations and commenced the evaluations. The agency released draft scope documents for each of these chemicals for public comment in March and April 2020 and finalized them in August and September 2020. Statutory timelines call for the EPA to publish final risk evaluations within three years of final designation, with a possible six-month extension. The EPA is striving to complete the risk evaluations as expeditiously as possible. Given the availability of resources and compounding nature of the failure to adequately resource this activity since the inception of the Lautenberg Act as described below and additional work needed related to the first 10 chemicals, some final risk evaluations likely will require more than three years and six months to complete. The EPA's resource needs are discussed in detail below.

EPA finalized the low-priority designation of 20 chemicals in February 2020. 10

Manufacturer-Requested Risk Evaluations (MRREs)¹¹

In May 2019, the EPA received manufacturer requests to conduct risk evaluations of diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP). In December 2019, the EPA granted both requests based on public comment and EPA review of the requests. In August 2021, the EPA released final scope documents for both chemicals, complying with statutory timelines.

In March 2020, the EPA received a manufacturer request to conduct a risk evaluation of octamethylcyclotetrasiloxane (D4). In October 2020, the EPA granted the request based on public comment and EPA's review of the requests. In September 2021, the EPA released draft scope documents for D4 for 45-day public review.

In November 2020, the EPA received an updated manufacturer request to conduct a risk evaluation of four chemical substances as a single category, the octahydro-tetramethyl-naphthalenyl-ethanone (OTNE) chemical category. In light of this request being submitted under TSCA section 6(h) and prior to the finalization of the EPA's 2016 risk evaluation rule and associated requirements for a manufacturer requested risk evaluation submission, the EPA is still working with the manufacturer to ensure the agency has the information necessary to perform a risk evaluation. 12

Status of Chemical Risk Evaluations Underway

The status of risk evaluations underway is summarized in Table 1 below. As a result of the resource constraints and policy decisions noted in this annual plan, the EPA currently is revising its schedule for revising and completing the risk evaluations listed in Table 1. The revised schedule is expected to be included in 2022 Annual Plan for Chemical Risk Evaluations Under TSCA, which EPA anticipates completing in January 2022.

⁹ See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca.

¹⁰ See https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0121-0009 and https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/low-priority-substances-under-tsca.

¹¹ For more information, see: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-manufacturer-requested-risk-evaluations-under-tsca.

¹² See https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0654-0108.

Table 1: Status of Existing Chemical Risk Evaluations

- Completed Wor

	Risk Evaluation (RE) Status					
Chemical	Initiate RE	Draft Scope	Final	Draft RE	Completed RE	
			Scope			
HPS Risk Evaluations Initiated in 2016						
Methylene Chloride	Dec. 2016		June 2017	Oct. 2019	June 2020	
1-Bromopropane	Dec. 2016		June 2017	Aug. 2019	Aug. 2020	
Cyclic Aliphatic Bromide Cluster (HBCD)	Dec. 2016		June 2017	June 2019	Sept. 2020	
Carbon Tetrachloride	Dec. 2016		June 2017	June 2019	Nov. 2020	
Trichloroethylene (TCE)	Dec. 2016		June 2017	Feb. 2020	Nov. 2020	
N-Methylpyrrolidone (NMP)	Dec. 2016		June 2017	Nov. 2019	Dec. 2020	
Perchloroethylene	Dec. 2016		June 2017	Apr. 2020	Dec. 2020	
1,4-dioxane	Dec. 2016		June 2017	June 2019	Dec. 2020	
C.I. Pigment Violet 29 (PV29)	Dec. 2016		June 2017	Nov. 2018, rev. Oct. 2020	Jan. 2021	
Asbestos Part I (Chrysotile)	Dec. 2016				Dec. 2021	
Asbestos Part II (Legacy Uses)	Dec. 2016	Dec. 2021				
HPS Risk Evaluations Initiated in 2019						
Tris(2-chloroethyl)phosphate (TCEP)	Dec. 2019	Apr. 2020	Aug. 2020			
Phosphoric acid, triphenyl ester (TPP)	Dec. 2019	Apr. 2020	Aug. 2020			
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-	Dec. 2019	Apr. 2020	Aug. 2020			
hexamethylcyclopenta [g]-2-benzopyran (HHCBA)		•				
p-Dichlorobenzene (PDCB)	Dec. 2019	Apr. 2020	Aug. 2020			
o-Dichlorobenzene (ODCB)	Dec. 2019	Apr. 2020	Aug. 2020			
Ethylene dibromide (EDB)	Dec. 2019	Apr. 2020	Aug. 2020			
Phthalic anhydride (PAD)	Dec. 2019	Apr. 2020	Aug. 2020			
1,1,2-Trichloroethane (1,1,2 TCA)	Dec. 2019	Apr. 2020	Aug. 2020			
1,2-Dichloropropane (1,2 DCP)	Dec. 2019	Apr. 2020	Aug. 2020			
1,1-Dichloroethane (1,1 DCA)	Dec. 2019	Apr. 2020	Aug. 2020			
1,2-Dichloroethane (1,2 DCA)	Dec. 2019	1	Aug. 2020			
4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	Dec. 2019	Apr. 2020	Aug. 2020			
Di-ethylhexyl phthalate – (1,2-Benzene-dicarboxylic acid, 1,2-bis-(2-ethylhexyl) ester)	Dec. 2019	Apr. 2020	Aug. 2020			
(DEHP)	D 2010		. 2020			
Formaldehyde (FDA)	Dec. 2019	Apr. 2020	Aug. 2020			
trans-1,2-Dichloroethylene (Trans 1,2 DCE)	Dec. 2019	Apr. 2020	Aug. 2020			
Dibutyl phthalate (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester) (DBP)	Dec. 2019	Apr. 2020	Aug. 2020			
Butyl benzyl phthalate – 1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester (BBP)	Dec. 2019	Apr. 2020	Aug. 2020			
Di-isobutyl phthalate – (1,2-Benzene-dicarboxylic acid, 1,2-bis-(2methylpropyl) ester) (DIBP)	Dec. 2019	Apr. 2020	Aug. 2020			
Dicyclohexyl phthalate (DCHP)	Dec. 2019	Apr. 2020	Aug. 2020			
1,3-Butadiene (BTD)	Dec. 2019	Apr. 2020	Aug. 2020			
Manufacturer-Requested Risk Evaluations Initiat			8 = = =			
Di-isodecyl phthalate (DIDP) – (1,2-	Dec. 2019	Nov. 2020	Aug. 2021			
benzenedicarboxylic acid 1,2-diisodecyl ester)			8 = 1 = 1			
Di-isononyl phthalate (DINP) – (1,2-	Dec. 2019	Nov. 2020	Aug. 2021			
benzenedicarboxylic acid, 1,2-diisononyl ester)						
Octamethylcyclotetra-siloxane (D4)	Oct. 2020	Sept. 2021				

Resources Necessary to Complete Risk Evaluations

The EPA lacks the capacity to successfully meet the deadlines for TSCA section 6 risk evaluations. On August 17, 2020, the EPA's Office of Inspector General (OIG) released the findings of its analysis of OCSPP's resources to meet TSCA's expectations. ¹³ In the OIG's judgement, "the EPA's TSCA risk evaluation capacity needs to dramatically increase to meet the statutory risk evaluation requirements of the 2016 TSCA amendments." ¹⁴

The OIG found that OPPT "did not have enough internal capacity to timely conduct the first set of ten TSCA risk evaluations." The OIG noted that OPPT received support from personnel outside the Risk Assessment Division (now named the Existing Chemical Risk Assessment Division), including staff members from OPPT's pollution prevention program and from the EPA's Office of Research and Development, but still missed the deadlines for most of first 10 existing chemical risk evaluations. The OIG estimated that for the EPA to have conducted 20 HPS risk assessments and four MRREs at a pace that allows the possibility of meeting TSCA's deadlines, the agency's TSCA risk evaluation capacity required an increase of at least 140 percent beginning in FY 2020. 15

On November 12, 2021, the OIG identified OCSPP's lack of capacity to fulfill its statutory obligations under TSCA as one of the EPA's top management challenges in FY 2022. ¹⁶ The OIG's estimate of the EPA's resource needs for risk evaluation reinforces the resource needs discussed below.

In the spring and summer of 2021, the EPA developed estimates of the resources necessary to conduct and complete TSCA risk evaluations according to the schedule set in the statute. The EPA's estimate is that an annual minimum of \$74.83 million (including Direct Pay, Non-Pay Resources, and Agency Overhead) would be required to meet this goal. This would represent an increase of nearly 100% over FY 2022 funding levels and an increase of more than 160% over the FY 2020 levels referred to by OIG.

In the FY 2022 President's Budget Request, the EPA requested an \$88,900 increase to non-pay funds and an additional 51.8 full-time equivalents (FTEs) for TSCA risk evaluation, risk management, data gathering, and prioritization. While the FTE portion of the request represents a major incremental investment in correcting the course to achieve what Congress envisioned for TSCA, operating under Continuing Resolutions (CRs) until mid-February 2022 (or beyond) will significantly impede the agency's ability to meet Congress's expectations. This is because under CRs, EPA lacks the ability to recruit, hire, and train new employees who would bring much-needed capacity and expertise to the TSCA program, and non-pay resources remain at the previous year's level. Because TSCA establishes strict deadlines, failing to provide the needed resources for the program in a timely manner will result in further delays of the work for which EPA is responsible under the statute.

The EPA's failure to request funding necessary to support timely completion of the first 10 risk evaluations led not only to failing to meet the statutory timeframes for completing nine of 10 of those evaluations but also to compounding impacts on the prospects of meeting deadlines for additional risk evaluations in the future. Severe resource shortfalls that have existed since the 2016 enactment of the Lautenberg Act impacted data gathering efforts to support the 20 high priority substances undergoing review such that data ordered under TSCA section 4 will be unavailable to the EPA well into the three year and six-month period for conducting evaluations. Systematic review of the available data related to these next 20 risk evaluations has been hampered by a lack of adequate resources as the scope of work doubled from 10 to 20 risk evaluations without a commensurate increase in resources. The additional

¹³ See https://www.epa.gov/sites/default/files/2020-08/documents/_epaoig_20200817-20-p-0247.pdf.

¹⁴ See https://www.epa.gov/system/files/documents/2021-11/certified_epaoig_20211112-22-n-0004.pdf.

 $^{^{15}} See \ https://www.epa.gov/system/files/documents/2021-11/certified_epaoig_20211112-22-n-0004.pdf,\ p.\ 30$

¹⁶ See https://www.epa.gov/system/files/documents/2021-11/certified epaoig 20211112-22-n-0004.pdf.

work described above related to the first 10 risk evaluations has added to the overall level of effort.

To accomplish as much as possible at current resource levels and to ensure a sustainable and manageable future workflow, the EPA will use a staggered approach for HPS chemical risk evaluations. Rather than attempting to start and end evaluation of 20 chemicals simultaneously, the EPA will stagger the workflow based on chemical properties and use, complexity of the information base and analysis, need for TSCA section 4 test orders, and other relevant factors. This approach will lead to a more manageable workload going forward, since the law requires the agency to initiate a new risk evaluation each time it completes one. The EPA will fulfill the statutory requirement to always have at least 20 EPA-initiated risk evaluations underway.

Additional funding could expand the EPA's research and development needs to meet TSCA's requirements to consider risk to "potentially exposed or susceptible subpopulations" through additional data collection efforts. For some chemicals, limited data exist to inform the Agency about unique exposure scenarios and cultural practices that may be relevant for TSCA risk assessment and management processes. Consistent with Executive Order (EO) 12898 of February 11, 1994, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations 17, EO 13985 of January 25, 2021, Advancing Racial Equity and Support for Underserved Communities through the Federal Government 18, and administration priorities, additional funding would allow for the EPA to better understand, consider, and address environmental justice concerns, including those of tribal and indigenous populations.

Table 2: Funding for Risk Evaluations from Completion of Prioritization Through Finalization

	FY 2021	FY 2022	FY 2023	Estimated
	(enacted)	(Pres Bud)	(Anticipated)	Annual Need
EPA-Initiated				
Number Underway	22	22	22	22
Direct Annual Cost	\$23.41	\$27.42	\$27.90	\$54.88
Total Annual Cost	\$28.09	\$32.90	\$33.48	\$65.86
Manufacturer-Requested: 50% Fee				
Number Underway	3	3	3	3
Direct Annual Cost	\$3.19	\$3.74	\$3.81	\$7.48
Total Annual Cost	\$3.83	\$4.49	\$4.57	\$8.98
Manufacturer-Requested: 100% Fee				
Number Underway	0	0	0	0
Direct Annual Cost				
Total Annual Cost				
Total				
Number Underway	25	25	25	25
Direct Annual Cost	\$26.60	\$31.16	\$31.71	\$62.36
Total Annual Cost	\$31.92	\$37.39	\$38.05	\$74.83

Fees

Under TSCA section 26(b), the EPA is authorized to set fees that ensure a sustainable source of funding

¹⁷ See https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf.

¹⁸ See https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.

to annually defray up to 25 percent of the costs to the Administrator of carrying out TSCA sections 4, 5 and 6, and of collecting, processing, reviewing, providing access to, and protecting from disclosure, as appropriate, chemical information under TSCA section 14. The authority to assess fees is conditioned on annual appropriations for EPA's Chemical Risk Review and Reduction (CRRR) Program, excluding fees, being held at least equal to the amount provided for FY 2014. ¹⁹

Although the EPA has authority to collect up to 25 percent of most implementation costs through fees, the fees rule failed to include the collection of fees from the first 10 TSCA risk evaluations and used artificially low baseline cost estimates based on lack of experience carrying out these activities and policy choices made by the previous administration. As a result of these circumstances, TSCA user fees paid to date by chemical companies total only 13% of implementation costs on average. For the same reasons, the total fees the EPA expects to collect for the 20 HPS risk evaluations started in FY 2019 represent about 12% of the resources needed.

In October 2018, the EPA published *Fees for Administration of Toxic Substances Control Act* ("fees rule"), which implemented the fee provisions of TSCA. ²⁰ Under the final rule, affected businesses began incurring fees in October 2018. The rule requires payment from manufacturers who submit information to EPA under TSCA Section 4, submit a notice, exemption application, or other information under TSCA Section 5 and who manufacture a chemical substance that is the subject of a risk evaluation under TSCA Section 6(b). Fees also apply to processors in certain circumstances under TSCA Sections 4 and 5. For each EPA-initiated risk evaluation, including those commenced for 20 high-priority chemicals in December 2019, a flat fee of \$1.35 million was shared among manufacturers of the chemical substance.

On January 11, 2021, the EPA proposed changes to certain provisions of the 2018 fees rule including new fee categories, definitions of obligated fee payers and exempted entities, timing for payment and consortia notification, and a production volume-based fee allocation for companies producing chemicals subject to EPA-initiated risk evaluation, as well as other changes.²¹ In 2022, the EPA plans to propose additional revisions to the 2018 TSCA fees rule to supplement the agency's proposal from January 2021 to ensure that TSCA fee amounts capture up to 25% of the costs of TSCA implementation activities.

The fees rule established fees for MRREs at either 50% or 100% of the actual costs associated with the evaluation, depending on whether the chemical is included in the *TSCA Work Plan for Chemical Assessments: 2014 Update.*²² For each of the three MRREs currently underway, a down payment of \$1.25 million was collected by the EPA. The remainder is due upon completion of the MRREs.

In June 2021, EPA released a revised final list of companies subject to fees for the 20 chemicals designated as high-priority substances for risk evaluation.²³ In FY 2021, the EPA received \$24.05 million in fees for the 20 HPS risk evaluations started in FY 2019. This amount equals 93.8% of the \$25.65 million total the Agency is expected to collect for these risk evaluations. The EPA estimates that the total cost of completing 20 HPS risk evaluations is \$209.53 million. Risk evaluation fees are collected as chemicals are prioritized, so the EPA will receive no additional fees funding for these chemicals.

Conclusion

This report serves as the 2021 Annual Plan for Chemical Risk Evaluations under TSCA as required under TSCA Section 26(n).

¹⁹ See TSCA section 26(b)(5).

 $^{^{20}}$ See https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0401-0072 and https://www.epa.gov/tscafees/fees-administration-toxic-substances-control-act.

²¹ See https://www.regulations.gov/search?filter=EPA-HQ-OPPT-2020-0493.

²² See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals#updates.

²³ See https://www.epa.gov/tsca-fees/final-list-fee-payers-next-20-risk-evaluations.