



WASHINGTON WATCH

EPA Prioritizes Chemicals for Risk Evaluation: Why This Matters

By Lynn L. Bergeson

The U.S. Environmental Protection Agency (EPA) released on March 20, 2019, a list of 40 chemicals for which EPA is initiating the prioritization process for risk evaluation. This article explains why the prioritization process is critically important for product manufacturers to monitor and manage, and how best to do so.

Background

Section 6(b)(2)(B) of the Toxic Substances Control Act (TSCA) requires that, as of three and a half years after enactment of the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (or by December 22, 2019), at least 20 high-priority chemicals be undergoing risk evaluations and at least 20 low-priority chemicals be designated by EPA. This legislative mandate was intentionally granular to address a gaping hole in old TSCA, namely the absence of any mandate to prioritize and evaluate “existing” chemical substances in commerce following enactment of old TSCA more than 40 years ago in 1976. Most readers will appreciate that the TSCA Chemical Inventory included well over 60,000 substances after TSCA was initially enacted, a number that swelled to over 80,000 when amended TSCA was enacted in 2016. Because existing chemicals, those chemicals in commerce in 1976, were “grandfathered,” all were allowed to continue in commerce without EPA review and assessment for risk of injury to human health or the environment. Structural deficiencies in old TSCA and EPA’s implementation of it impeded the systematic prioritization and review of existing chemicals, a deficiency that was one of several rallying cries for amended TSCA’s enactment in 2016.

The [March 21, 2019, Federal Register notice](#) from EPA provides a general explanation of why EPA chose these particular chemical substances and information on the data sources that EPA plans to use to support the designation (EPA, 2019a). EPA also provided a 90-day comment period during which interested persons may submit relevant information on these chemical substances. Comments were due by June 19, 2019.

High-Priority Candidate Chemical Substances

On September 28, 2018, EPA released the general approaches that the Office of Pollution Prevention and Toxics (OPPT) may use to identify potential candidate chemicals for prioritization under TSCA (EPA, 2018a; EPA, 2018b). To identify candidates for designation as high-priority substances, EPA states in the March 21, 2019, *Federal Register* notice that it “primarily looked to the TSCA Work Plan for Chemical Assessments: 2014 Update (2014 TSCA Work Plan)” (EPA, 2019a, p. 10493). EPA surveyed the information and checked quality data elements in a step-wise approach intended to ensure “responsible and timely completion of the process according to TSCA timelines” (EPA, 2019a, p. 10493). Additionally, the Agency opened dockets for each of the 2014 TSCA Work Plan chemicals, and an additional docket for non-2014 TSCA Work Plan chemicals, to allow for public comment on the prioritization of these chemicals.

The sources of information included:

- **Type 1 Sources:** Existing databases (and dashboards) that allow the user to sift through information using a graphical user-interface, a direct query, such as Structured Query Language (SQL), or web service Application Programming Interface (API). EPA’s National Center for Computational Toxicology’s Chemistry Dashboard is one of the several examples of a Type 1 source.

- **Type 2 Sources:** Additional details from existing information from public and nonpublic (*i.e.*, confidential business information (CBI)) sources that are maintained by competent authorities. This includes supporting information from other EPA program offices and state and federal agencies, including assessments or evaluations from various United States and international organizations (*e.g.*, including, but not

limited to, EPA's Integrated Risk Information System (IRIS) Assessments, EPA's Office of Water, EPA's Office of Air and Radiation, EPA's High Production Volume (HPV) Challenge Program, International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), National Institute for Occupational Safety and Health (NIOSH), Organization for Economic Cooperation and Development (OECD), Agency for Toxic Substances and Disease Registry (ATSDR), and California Environmental Protection Agency (Cal EPA)).

- **Type 3 Sources:** Initial searches of additional sources of information within the public and gray literature domains that are not available from Type 1 and 2 sources (*e.g.*, searches in PubMed, ToxNet, other U.S. government and international websites). (EPA, 2019a, p. 10493).

EPA evaluated the information across several data elements and reviewed the chemical substances for data availability across all data elements (*e.g.*, hazard, exposure, uses, physicochemical, and environmental fate and transport properties). According to EPA, it considered chemical similarity, similar identified functions (*e.g.*, solvents, phthalates, flame retardants), existing OPPT work (*e.g.*, experience gained from the first ten chemicals to undergo risk evaluation), and other information as identified in available assessments (*e.g.*, IRIS and the European Chemicals Agency (ECHA)) and public literature.

EPA notes that in the absence of measured data on chemicals being evaluated, it may use alternative means or new approach methods (NAM) to obtain relevant data. These NAMs can reduce vertebrate testing, consistent with TSCA Section 4(h)(1)(A). EPA states that it intends to use this approach to the extent practicable and scientifically justified.

To identify chemical substances, EPA considered information such as the 2016 Chemical Data Reporting (CDR) reported uses and products as a surrogate for complexity of information to inform prioritization and risk evaluation. EPA considered the release and use information for these chemicals and screened them according to the types of industrial uses and types of products where the chemicals were used, as reported in the 2016 CDR. According to EPA, it "considers a chemical with fewer unique uses as a

lower work load and a chemical with multiple uses reported as a higher work load" (EPA, 2019a, p. 10493).

EPA is initiating the prioritization process for the following 20 chemicals as candidates for designation as high-priority substance candidates, as listed and with the status provided on EPA's web page, "[List of Chemicals Undergoing Prioritization](#)" (EPA, 2019b).

Chemical Name	CAS Number	Docket Number	Status*
p-Dichlorobenzene	106-46-7	EPA-HQ-OPPT-2018-0446	Initiated
1,2-Dichloroethane	107-06-2	EPA-HQ-OPPT-2018-0427	Initiated
trans-1,2-Dichloroethylene	156-60-5	EPA-HQ-OPPT-2018-0465	Initiated
o-Dichlorobenzene	95-50-1	EPA-HQ-OPPT-2018-0444	Initiated
1,1,2-Trichloroethane	79-00-5	EPA-HQ-OPPT-2018-0421	Initiated
1,2-Dichloropropane	78-87-5	EPA-HQ-OPPT-2018-0428	Initiated
1,1-Dichloroethane	75-34-3	EPA-HQ-OPPT-2018-0426	Initiated
Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2- dibutyl ester)	84-74-2	EPA-HQ-OPPT-2018-0503	Initiated
Butyl benzyl phthalate (BBP) - 1,2-Benzene-dicarboxylic acid, 1- butyl 2(phenylmethyl) ester	85-68-7	EPA-HQ-OPPT-2018-0501	Initiated
Di-ethylhexyl phthalate (DEHP) - (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)	117-81-7	EPA-HQ-OPPT-2018-0433	Initiated
Di-isobutyl phthalate (DIBP) - (1,2-Benzene-dicarboxylic acid, 1,2- bis-	84-69-5	EPA-HQ-OPPT-2018-0434	Initiated

(2methylpropyl) ester)			
Dicyclohexyl phthalate	84-61-7	EPA-HQ-OPPT-2018-0504	Initiated
4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	79-94-7	EPA-HQ-OPPT-2018-0462	Initiated
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	EPA-HQ-OPPT-2018-0476	Initiated
Phosphoric acid, triphenyl ester (TPP)	115-86-6	EPA-HQ-OPPT-2018-0458	Initiated
Ethylene dibromide	106-93-4	EPA-HQ-OPPT-2018-0488	Initiated
1,3-Butadiene	106-99-0	EPA-HQ-OPPT-2018-0451	Initiated
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1222-05-5	EPA-HQ-OPPT-2018-0430	Initiated
Formaldehyde	50-00-0	EPA-HQ-OPPT-2018-0438	Initiated
Phthalic anhydride	85-44-9	EPA-HQ-OPPT-2018-0459	Initiated

*Status is listed as either:

- Initiated—The first step of the prioritization process, and the chemical is currently undergoing a screening-level review of reasonably available information to inform its priority designation;
- Proposed—The second step of the prioritization process, when EPA proposes a chemical's designation as either high or low priority for risk evaluation; or
- High/Low—The final step of the prioritization process. This chemical has been designated as high or low priority for risk evaluation.

Low-Priority Candidate Chemical Substances

According to EPA, it began with more than 30,000 chemicals listed as active in the April 2018 interim update of the TSCA Chemical Inventory. The Agency then applied a series of filtering steps to identify potential low-priority substance candidates. EPA identified potential low-priority substance candidates “based on low-hazard, across a range of endpoints, as the initial criterion since EPA knew the data on hazard would be the most readily available” (EPA, 2019a, p. 10495).

EPA then narrowed the candidate pool to chemicals that had been evaluated by a government body like EPA or an OECD member nation. EPA’s [Safer Chemical Ingredients List](#) (SCIL) and Chemical Assessment Management Program (ChAMP), as well as the OECD Screening Information Data Sets (SIDS), served as sources of government-evaluated chemicals.

EPA states that as a next filtering step and to increase confidence in the information on hazard, conditions of use, and exposure, it filtered the pool of approximately 1,600 chemicals to approximately 200 substances having discretely defined structures. According to EPA, “[d]ata on chemicals with discrete structures, as opposed to those with variable structures, are more reliable and easily compared because of the certainty a definitive molecular structure provides in assessing hazard, conditions of use, and exposure” (EPA, 2019a, 10495). EPA further filtered the chemicals with discrete structures and selected those with the most available data, narrowing the pool to about 75 chemicals “with low-hazard status among an internationally accepted set of endpoints” (EPA, 2019a, 10495). EPA applied a final screen by conducting a literature search to update and verify candidate information for reliability, completeness, and consistency. With a set of high-quality data relevant to a potential designation as a low-priority substance, EPA states that it reduced the candidate pool to 20 chemical substances. According to the *Federal Register* notice, EPA will make transparent literature search documentation available at the proposal phase for the 20 low-priority substance candidates. EPA intends to update and refine its initial review based on data sources identified by the public during the comment period and, where permitted by TSCA Section 14 and subject to EPA’s confidentiality regulations at 40 Code of Federal Regulations (CFR)

Part 2, Subpart B, the Agency intends to make this information publicly available for the 20 initiated chemicals at proposal.

EPA used the following data sources to obtain “reasonably available” information for evaluating candidate low-priority substances consistent with TSCA Section 6(b)(1)(B) and the implementing regulations. EPA encourages submission of additional information relevant to low-priority substance designation that stakeholders believe may not be found in the sources listed below.

- **Data Sources:** EPA intends to search for and review literature from primary literature databases and gray literature and additional search strategies; and
- **NAMs and Analogous Chemical Data:** In the absence of measured data on chemicals being evaluated, EPA may use alternative means or NAMs to obtain relevant data. These NAMs can reduce vertebrate testing, consistent with TSCA Section 4(h)(1)(A). EPA intends to use this approach to the extent practicable and scientifically justified. EPA will consider closely related, analogous chemicals, or analogs, and use data from these chemicals to demonstrate the suitability of a chemical for proposal as a low-priority substance where appropriate.

EPA is initiating the prioritization process for the following 20 chemicals as candidates for designation as low-priority substance candidates, as listed and with the status provided on EPA’s web page, [“List of Chemicals Undergoing Prioritization”](#) (EPA, 2019b):

Chemical Name	CAS Number	Docket Number	Status*
1-Butanol, 3-methoxy-, 1-acetate	4435-53-4	EPA-HQ-OPPT-2019-0106	Initiated
D-gluco-Heptonic acid, sodium salt (1:1), (2.xi.)-	31138-65-5	EPA-HQ-OPPT-2019-0107	Initiated
D-Gluconic acid	526-95-4	EPA-HQ-OPPT-2019-0108	Initiated
D-Gluconic acid, calcium salt (2:1)	299-28-5	EPA-HQ-OPPT-2019-0109	Initiated

D-Gluconic acid, .delta.-lactone	90-80-2	EPA-HQ-OPPT-2019-0110	Initiated
D-Gluconic acid, potassium salt (1:1)	299-27-4	EPA-HQ-OPPT-2019-0111	Initiated
D-Gluconic acid, sodium salt (1:1)	527-07-1	EPA-HQ-OPPT-2019-0112	Initiated
Decanedioic acid, 1,10-dibutyl ester	109-43-3	EPA-HQ-OPPT-2019-0113	Initiated
1-Docosanol	661-19-8	EPA-HQ-OPPT-2019-0114	Initiated
1-Eicosanol	629-96-9	EPA-HQ-OPPT-2019-0115	Initiated
1,2-Hexanediol	6920-22-5	EPA-HQ-OPPT-2019-0116	Initiated
1-Octadecanol	112-92-5	EPA-HQ-OPPT-2019-0117	Initiated
Propanol, [2-(2-butoxymethylethoxy)methylethoxy]-	55934-93-5	EPA-HQ-OPPT-2019-0118	Initiated
Propanedioic acid, 1,3-diethyl ester	105-53-3	EPA-HQ-OPPT-2019-0119	Initiated
Propanedioic acid, 1,3-dimethyl ester	108-59-8	EPA-HQ-OPPT-2019-0120	Initiated
Propanol, 1(or 2)-(2-methoxymethylethoxy)-, acetate	88917-22-0	EPA-HQ-OPPT-2019-0121	Initiated
Propanol, [(1-methyl-1,2-ethanediyl)bis(oxy)]bis-	24800-44-0	EPA-HQ-OPPT-2019-0122	Initiated
2-Propanol, 1,1'-oxybis-	110-98-5	EPA-HQ-OPPT-2019-0123	Initiated
Propanol, oxybis-	25265-71-8	EPA-HQ-OPPT-2019-0124	Initiated
Tetracosane, 2,6,10,15,19,23-hexamethyl-	111-01-3	EPA-HQ-OPPT-2019-0125	Initiated

*The status indicators of "initiated," "proposed," and high/low" are the same as those described previously in this column.

Relevant Information

EPA requests that interested persons “voluntarily submit” relevant information, including, but not limited to, information that may inform the screening review conducted pursuant to 40 CFR Section 702.9(a) and consistent with the scientific standard of TSCA Section 26(h), as follows:

- The chemical substance’s hazard and exposure potential;
- The chemical substance’s persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations which the submitter believes are relevant to the prioritization;
- Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);
- The chemical substance’s conditions of use or significant changes in conditions of use, including information regarding trade names;
- The chemical substance’s production volume or significant changes in production volume; and
- Any other information relevant to the potential risks of the chemical substance that might be relevant to the designation of the chemical substance’s priority for risk evaluation (EPA, 2019a, p. 10498).

EPA states that if the information is publicly available, citations are sufficient (including, but not limited to title, author, date of publication, and publication source), and the submission does not need to include copies of the information. A person seeking to protect from disclosure as confidential business information (CBI) any information that person submits under TSCA must assert and substantiate a claim for protection from disclosure concurrent with submission of the information, in accordance with the requirements of TSCA Section 14. While EPA may consider CBI when conducting its review under 40 CFR Section 702.9(a), the Agency “encourages submitters to minimize claims for protection from disclosure

wherever possible to maximize transparency in EPA's screening review" (EPA, 2019a, 10498).

Discussion

In issuing the March notice concerning initiation of prioritization for 40 chemicals, EPA met yet another of the many required milestones under amended TSCA. As required by TSCA Section 6(b) and consistent with the prioritization screening review procedure at 40 CFR Section 702.9(a), EPA must undertake a process, including requesting public comment at specific junctures, leading to designation of at least 20 high- and 20 low-priority chemicals for risk evaluation. This process must be completed by December 2019. Subsequent steps in the process include the Agency proposing and taking comment on each designation as a high- or low-priority substance, and then EPA issuing in final the chemical designations as high or low priority.

The list of chemicals suggested for high priority consist of several groups of related chemicals (eight halogenated organics, including two dichlorobenzenes, three dichloroethanes, a dibromoethane, a dichloropropane, and a dichloroethylene, and five phthalates) and seven other chemicals, including three flame retardants (both halogenated and non-halogenated), two chemicals used largely as chemical intermediates (butadiene and phthalic anhydride), a fragrance ingredient, and formaldehyde. None of the chemicals is particularly surprising although the decision to include formaldehyde as a prioritization process candidate may strike some as odd given that it has been under intense scrutiny for years by the IRIS program and the OPPT completed rulemaking on formaldehyde in wood products in 2016. In conducting the risk evaluation on formaldehyde, EPA can and is expected to use the IRIS assessment along with other existing hazard and exposure assessments.

Perhaps the most interesting aspect of the notice concerns the 20 low-priority chemicals that EPA has identified for consideration in the prioritization process. It will be easier to support low-risk conclusions if such conclusions can be based solely on a hazard determination, obviating the need for an exposure assessment. The downside in taking this approach is that EPA has left no margin for error in meeting the deadline requirement for

designating 20 low-priority chemicals. EPA describes the low-priority candidates as “relatively rich in data on hazard” (EPA, 2019a, p. 10495); the Agency must be confident that the information available to it on these 20 chemicals when it comes time to issue its proposal and subsequently to release in final such a designation meets the “sufficient to establish” standard. This means that if, at the end of the prioritization process, EPA cannot meet the “sufficient to establish” standard for any of the proposed low-priority substances, EPA will confront having to designate such substances as high priority and proceed with risk evaluation with additional substances (*i.e.*, more than the expected 30 -- the first ten and the 20 proposed high-priority substances).

As for the high-priority candidates, several points warrant mention here. First, regardless of the risk evaluation outcome, stakeholders need to manage the optics of making, distributing, and/or using a “high-priority” chemical. It may be the case that its designation as such is a non-event. Or it may be otherwise. The point is, be prepared to communicate clearly and immediately what a high-priority chemical is and is not.

Second, the source of the candidate nominees is not a mystery. It is the 2014 Work Plan Chemicals list, a list of over 90 substances that everyone in the chemical community should know by now (five years later). If a chemical near and dear to you and/or your company is among the “chosen,” you may wish to think about the implications of its listing on the 2014 Work Plan list and plan accordingly.

References

EPA (2018a). EPA takes first steps in identifying next group of chemicals for risk evaluation under TSCA. News Releases from Headquarters, Chemical Safety and Pollution Prevention. 09/28/2018. Available at: <https://www.epa.gov/newsreleases/epa-takes-first-steps-identifying-next-group-chemicals-risk-evaluation-under-tsca>

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