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EPA Releases List of 40 Chemicals Undergoing Prioritization for Risk Evaluation

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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. Section 6(b)(2)(B) of the Toxic Substances Control Act (TSCA) requires that, as of three and a half years after enactment (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. In a March 21, 2019, *Federal Register notice*, EPA provides a general explanation of why it chose these chemical substances and information on the data sources that EPA plans to use to support the designation. EPA is providing a 90-day comment period during which interested persons may submit relevant information on these chemical substances. Comments are due **June 19, 2019**.

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High-Priority Candidate Chemical Substances

As reported in our October 3, 2018, memorandum, "EPA Releases Working Approach for Identifying Potential Candidate Chemicals for Prioritization under TSCA," 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. To identify candidates for designation as high-priority substances, EPA states in the *Federal Register* notice that it "primarily looked to the TSCA Work Plan for Chemical Assessments: 2014 Update (2014 TSCA Work Plan)." 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." Additionally, EPA 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 U.S. 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)); and

- 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 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 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":

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-(2methylpropyl)	84-69-5	EPA-HQ-OPPT-2018-0434	Initiated

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 over 30,000 chemicals listed as active on the April 2018 interim update of the TSCA Chemical Inventory. EPA 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 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 Chemicals 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 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 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 confidentiality regulations at 40 C.F.R. Part 2, Subpart B, 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 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":

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	108-59-8	EPA-HQ-OPPT-	Initiated

ester		2019-0120	
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 above.

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 C.F.R. 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 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 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 C.F.R. Section 702.9(a), EPA “encourages submitters to minimize claims for protection from disclosure wherever possible to maximize transparency in EPA’s screening review.”

Commentary

EPA met another of the required milestones under amended TSCA in issuing this notice concerning initiation of prioritization for 40 chemicals. As required by TSCA Section 6(b) and consistent with the prioritization screening review procedure at 40 C.F.R. 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**. The March 21, 2019, *Federal Register* notice initiates this process and interested persons have until **June 19, 2019**, to comment and to submit relevant scientific information to EPA concerning these 40 chemicals and their suitability for prioritization. Subsequent steps in the process include EPA proposing and taking comment on each designation as a high- or low-priority substance, and then EPA finalizing 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. From our perspective, 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 OPPT completed rulemaking on formaldehyde in wood products in 2016 (81 Fed. Reg. 89724). Nonetheless, the TSCA risk evaluation process is separate and distinct from that under IRIS and it is not unreasonable to start the TSCA process at the beginning looking at all known or reasonably foreseeable conditions of use. Initiation of the TSCA risk evaluation step for formaldehyde requires that EPA designate it as a high-priority substance, an outcome that, while seemingly assured, nonetheless needs to be elicited by the Section 6(b) prioritization process. 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. We applaud EPA's focus on low hazard substances. 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. Readers may recall that Section 6(b)(1)(B)(ii), concerning low-priority substances, requires that EPA designate a chemical as a low priority "if [EPA] concludes, based on *information sufficient to establish*…that such substance does not meet" the high-priority standard (emphasis added). As we commented during the legislative process that produced the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the "sufficient to establish" phrase creates a relatively high bar that must be satisfied in designating a low-priority chemical, a decision that is subject to legal challenge (Section 19(a)(1)(C)). We note that EPA describes the low-priority candidates as "relatively rich in data on hazard"; EPA 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). Some readers may recall that Section 6(b)(1)(C) allows EPA to extend the prioritization deadline for three months subject to the additional requirement "that if the information available to [EPA] at the end of such extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, [EPA] shall designate the chemical substance as a high-priority substance." This provision, however, applies to cases for which EPA has required the development of new information under Section 4(a)(2)(B), a step that EPA has not initiated on any of these low-priority candidates. It is possible, but not likely, that manufacturers of low-priority substances could complete testing to fill in such data gaps within the total 12 months (including an extension) for prioritization.

Time will tell how EPA handles any "close calls" in proposing and then designating the low-priority chemicals. In the future, EPA might only propose potential low-priority substances when it has capacity to review them as high priority if the supporting data set is insufficient. In addition, taking a number of low-priority substances through the process will give EPA better insight into what data will be necessary to support a low-priority designation. EPA may then begin to exercise its new Section 4 authority to require testing on substances that EPA anticipates designating for prioritization to ensure a record exists to support a low-priority conclusion.

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