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Examination of EPA's Risk Assessment of Chemicals in the 21st Century

A Panel Discussion

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ABSTRACT

Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the United States Environmental Protection Agency (USEPA) evaluates potential risks from new and existing chemicals and acts to address any unreasonable risks chemicals may have on human health and the environment, which includes much needed improvements in the area of risk-based chemical assessments. In July 2019, USEPA began the second round of talks on the risk-based chemical evaluations, which are still in progress. The purpose of the risk evaluations is to determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible sub-population. This talk will discuss the state of the risk evaluations undertaken to date, including decisions undertaken and effects of such actions on defending toxic tort matters in the future.

OVERVIEW OF THE FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the Act) was signed into law. This act amended the Toxic Substances Control Act (TSCA) and included much needed improvements such as:

- Mandatory requirement for USEPA to evaluate existing chemicals with clear and enforceable deadlines;
- Risk-based chemical assessments;
- Increased public transparency for chemical information; and
- Consistent source of funding for USEPA to carry out the responsibilities under the new law.

There are six key provisions in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, including, existing chemicals, new chemicals, confidential business information, source of sustained funding, federal-state partnership, and mercury export and disposal. For existing chemicals, the Act requires USEPA to establish a risk-based process to determine which chemicals it will prioritize for assessment, identifying them as either "high" or "low" priority substances. High priority substances are those chemicals that may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure (e.g., inhalation, ingestion), including susceptible subpopulations. Designation of a substance as a high priority chemical triggers a requirement and deadline for the USEPA to complete a risk evaluation to determine the chemical's safety. Risk evaluations conducted under the Act excludes consideration of costs or non-risk factors and must consider risks to susceptible and highly exposed populations. When unreasonable risks are identified, USEPA must take final risk management action within two years, or four years if an extension is needed. Costs and availability of alternatives can be considered by USEPA when determining the appropriate

action to address unreasonable risks, and any action, including bans or phase-outs, must begin as quickly as possible but no later than five years after the final regulation. Low priority chemicals are those substances USEPA determines that do not meet the high-priority standard, and requires no further action by USEPA, unless further information becomes available elevating the substance to the high priority classification. The Act requires USEPA to have 10 ongoing risk evaluations within the first 180 days and 20 ongoing risk evaluations within 3.5 years. Manufacturers of existing chemicals can request USEPA to evaluate specific chemicals, and they must pay 50% to 100% of the costs depending if the chemical is on the TSCA Workplan, or not on the TSCA Workplan, respectively. Manufacturer-requested assessments must account for between 25% to 50% of the number of ongoing high-priority risk evaluations, but do not count towards the minimum of 20 ongoing risk evaluations. The Act gives USEPA the authority to obtain testing information for prioritizing or conducting risk evaluations on a chemical, to promote the use of non-animal alternative testing methodologies, and to fast-track persistent, bioaccumulative and toxic chemicals.

For new chemicals, the Act requires USEPA to perform a pre-market review and make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before it is allowed into the marketplace.

The Act also established new substantiation requirement for certain types of confidentiality claims from companies. It requires USEPA to review and make determinations on all new confidentiality claims for the identify of chemicals and a subset of other types of confidentiality claims, and to review past confidentiality claims for chemical identity to determine if the claim is still warranted.

The new law allows USEPA to collect up to $25 million annually in user fees from chemical manufacturers and processors when they submit test data for USEPA review, submit a premanufacture notice for a new chemical or a notice of new use, manufacture or process a chemical that is the subject of a risk evaluation, or request that USEPA conduct a chemical risk evaluation. The Act provides a federal-state partnership, which allows: states to act on any chemical, or particular uses or risk from a chemical, that USEPA has not yet addressed; grandfathers existing state requirements prior to April 22, 2016; preserves existing and new state requirements under state laws in effect on August 31, 2003; preserves states environmental authorities related to air, water, waste disposal and treatment; and allows states and the federal government to co-enforce identical regulations. Finally, the Act amends requirements for mercury export and disposal.

PROPOSED HIGH-PRIORITY SUBSTANCES

On August 23, 2019 USEPA proposed to designate 20 chemicals as high—priority substances for risk evaluation and asked for comments on the proposed designations by November 21, 2019. The proposed high priority candidate chemicals are as follows (Table 1):

Table 1: Proposed High Priority Substances

Chemical Name (CAS No.)	Docket Number (EPA-HQ-OPPT-2018-)	Status
p-Dichlorobenzene (106-46-7)	0446	Proposed
1,2-Dichloroethane (107-06-2)	0427	Proposed
trans-1,2-Dichloroethylene (156-60-5)	0465	Proposed
o-Dichlorobenzene (95-50-1)	0444	Proposed
1,1,2-Trichloroethane (79-00-5)	0421	Proposed
1,2-Dichloropropane (78-87-5)	0428	Proposed
1,1-Dichloroethane (75-34-3)	0426	Proposed
Dibutyl phthalate (DBP) (84-74-2)	0503	Proposed
Butyl benzyl phthalate (BBP) (85-68-7)	0501	Proposed
Di-ethylhexyl phthalate (DEHP) (117-81-7)	0433	Proposed
Di-isobutyl phthalate (DIBP) (84-69-5)	0434	Proposed
Dicyclohexyl phthalate (84-61-7)	0504	Proposed
4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA) (79-94-7)	0462	Proposed
Tris(2-chloroethyl) phosphate (TCEP) (115-96-8)	0476	Proposed
Phosphoric acid, triphenyl ester (TPP) (115-86-6)	0458	Proposed
Ethylene dibromide (106-93-4)	0488	Proposed
1,3-Butadiene (106-99-0)	0451	Proposed
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethyl-cyclopenta[g]-2 benzopyran (HHCB) (1222-05-5)	0430	Proposed
Formaldehyde (50-00-0)	0438	Proposed
Phthalic anhydride (85-44-9)	0459	Proposed

The rational for USEPA listing these chemicals as high-priority substances is varied and provided in the supporting documents found within each chemical's Docket Number. For example, the listing of p-dichlorobenzene as a high-priority substance was due to USEPA's determination that the manufacturing, processing, distribution, use and disposal of p-dichlorobenzene may result in the presence of the chemical in surface water and groundwater, ingestion of the chemical in drinking water, inhalation of the chemical from air releases, and exposure to workers, consumers and the general population, including children. Additionally, the USEPA identified potential environmental (e.g., aquatic toxicity and terrestrial toxicity) and human health hazards (e.g., acute toxicity, repeated dose toxicity, developmental toxicity, irritation/corrosion, carcinogenicity, neurotoxicity, and observations in epidemiological studies or biomonitoring studies.) (Proposed Designation of p-Dichlorobenzene (CASRN 106-46-7) as a High-Priority Substance for Risk Evaluation (see Docket Number). Similarly, although not identically, the listing of formaldehyde as a high-priority substance was based on USEPA's determination that the manufacturing, processing, distribution, use, and disposal of formaldehyde may result in the presence of the chemical in surface water, groundwater, and drinking water, from the

inhalation of the chemical from releases to air, and exposure to workers and the general population, including children. USEPA also expects potential environmental (e.g., aquatic toxicity, terrestrial toxicity) and human health hazards, including acute toxicity, irritation/corrosion in the upper respiratory tract, eyes, and skin, dermal and respiratory sensitization, carcinogenicity, and genetic toxicity (Proposed Designation of Formaldehyde (CASRN 50-00-0) as High-Priority Substance for Risk Evaluation (see Docket Number). As a final example, the listing of dicyclohexyl phthalate as a high-priority substance was based on USEPA's determination for the potential finding of this chemical in surface water, ground water, and drinking water, and inhalation resulting from releases to air, on potential human health hazards (e.g., repeated dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, toxicokinetic, and irritation/corrosion), but not on potential environmental hazards, as USEPA has not identified any concerns for aquatic or terrestrial organisms due to exposure to dicyclohexyl phthalate (Proposed Designation of Dicyclohexyl Phthalate (CASRN 84-61-7) as a High-Priority Substance for Risk evaluation (see Docket Number).

PROPOSED LOW-PRIORITY SUBSTANCES

On August 15, 2019 USEPA proposed to designate 20 chemicals as low—priority substances for risk evaluation and asked for comments on the proposed designations by November 13, 2019. The proposed low priority candidate chemicals are as follows (Table 2):

Table 2: Proposed Low-Priority Chemicals

Chemical Name (CAS No.)	Docket Number (EPA-HQ-OPPT-2019-)	Status
1-Butanol, 3-methoxy-, 1-acetate (4435-53-4)	0106	Proposed
D-gluco-Heptonic acid, sodium salt (1:1), (2.xi.)- (31138-65-5)	0107	Proposed
D-Gluconic acid (526-95-4)	0108	Proposed
D-Gluconic acid, calcium salt (2:1) (299-28-5)	0109	Proposed
D-Gluconic acid, .delta.-lactone (90-80-2)	0110	Proposed
D-Gluconic acid, potassium salt (1:1) (299-27-4)	0111	Proposed
D-Gluconic acid, sodium salt (1:1) (527-07-1)	0112	Proposed
Decanedioic acid, 1,10-dibutyl ester (109-43-3)	0113	Proposed
1-Docosanol (661-19-8)	0114	Proposed
1-Eicosanol (629-96-9)	0115	Proposed
1,2-Hexanediol (6920-22-5)	0116	Proposed
1-Octadecanol (112-92-5)	0117	Proposed
Propanol, [2-(2-butoxymethylethoxy) methylethoxy]- (55934-93-5)	0118	Proposed
Propanedioic acid, 1,3-diethyl ester (105-53-3)	0119	Proposed
Propanedioic acid, 1,3-dimethyl ester (108-59-8)	0120	Proposed

Propanol, 1(or 2)-(2-methoxymethylethoxy)-acetate (88917-22-0)	0121	Proposed
Propanol, [(1-methyl-1,2-ethanediyl) bis(oxy]bis- (24800-44-0)	0122	Proposed
2-Propanol, 1,1'-oxybis- (110-98-5)	0123	Proposed
Propanol, oxybis- (25265-71-8)	0124	Proposed
Tetracosane, 2,6,10,15,19,23-hexamethyl- (111-01-3)	0125	Proposed

The rationale used for listing each of these substances as low-priority chemicals was USEPA's determination that, after reviewing the available database for each chemical, the substance did not meet the statutory criteria for a high-priority substance. The supporting document for each of the low-priority chemicals can be found in their respective Docket Number.

LOOKING FORWARD

Once the proposed high-priority and low-priority chemicals have gone through their respective comment periods, USEPA will initiate and complete a risk evaluation for the high-priority chemicals to determine the chemical's safety. Although the Act requires USEPA to use the best available science, that term is not defined in the Act. What information goes into the risk evaluation will determine the chemical's safety and fate, and it is here where potential issues may arise. Understanding what information was incorporated, or eliminated, from a risk evaluation is critical and may have profound influence on USEPA's determination for a chemical, which ultimately may drive litigation in the future.